The Clinic for People Without Health Insurance
Ben Wofford, M.D.
105 N. Main Avenue, Newton, NC 28658
(828) 466-2330 Fax (828) 466-2338

February 8, 2005

REGISTERED MAIL

Occupational Safety and Health Administration
4407 Bland Rd., Suite 210,
Raleigh, NC 27609

Re: Exposure of several employees to a neurotoxin at Royal Comfort Seating Plant #2 at 633 4th Street Place SW, Conover, NC 28613

Encl: A copy of my letter to Mr. Willie Cockrell, CEO, Royal Comfort Seating, PO Box 235, Taylorsville, NC 28681. Phone (828) 632-2862

A copy of the enclosed letter is being sent to you on advice of counsel. The letter itself is self-explanatory. Some elaboration, however, seems appropriate.

I learned yesterday that great efforts are underway in the Conover plant to correct the problem. I do not know Mr. Cockrell personally, but my son, Chief Pilot of CommScope, world's largest coaxial cable manufacturer, does know Mr. Cockrell, and he expressed the private opinion that Mr. Cockrell was probably unaware of the problem until one of my earlier letters found its way to him.

Furthermore, I was exceedingly reluctant to send a copy of this letter to you, and did so only on the advice of counsel. There are other problems at the Conover plant, one being a general lack of cleanliness – especially in the company cafeteria. I would hate to see this plant's multiple shortcomings result in its being shut down. A lot of people would be out of a job. Many are my patients and are already in dire straights economically.

That said, I am particularly distressed at the terrible physical condition of one particular employee, a Latino. He is totally disabled now and may well die as a result of his exposure to this neurotoxin. Almost as bad, but not quite, is the plight of a Latino woman. She is the sole support of herself and three children. She too is unlikely to find work if the effects of the neurotoxin are irreversible, as my Neurological consultants thinks they may be. What is to become of this little family? It breaks my heart.

Well, enough said.

Sincerely,

Ben Wofford, M.D.
CC: Mr. Cockrell, CEO, Royal Comfort Seating

Ben Wofford, M.D.
105 N. Main Avenue, Newton, NC 28658
(828) 466-2330
Fax (828) 466-2338

February 7, 2005

Mr. Willie Cockrell, CEO
Royal Comfort Seating
PO Box 235
Taylorsville, NC 28681

REGISTERED MAIL

Dear Mr Cockrell:

I am writing to you and sending a copy (reluctantly) to Occupational Safety and Health Administration on the advice of counsel, failure to do so being tantamount to professional negligence and in violation of state and federal statues.

Seven of your company's employees from have come to my office with signs and symptoms arising from exposure to a **neurotoxin** at your Plant #2 at 633 4th Street Place SW, Conover, NC 28613. I understand that other employees are similarly affected

The source of this toxin is apparently a cleaner and/or spray adhesive. All seven affected employees were assigned to a "glue line" where these items were used in an ***unventilated*** area. A copy of each can's label is attached. **Note the warning on the label.**

All seven people presented with unsteady gait, weakness (especially of the legs), pain, and poor balance. Hyperreflexia, Romberg's Sign and inability to walk on the toe, heel, or in tandem were the principal findings on examination.

Three of these people are more severely affected than the others. Each was given a letter for delivery to the Personnel Office of your plant in Conover. (A representative copy is attached.) I am particularly concerned about one, and his letter indicated that he was the most severely affected person of the group. Indeed, he may die as a result of this exposure. His initial visit was on January 31. On follow-up February 5, his condition had deteriorated markedly.

I discussed these cases with one of my Neurology consultants, who expressed the fear that this damage may be irreversible. Let us pray that this is not so.

It is pertinent to point out here that MRIs, CAT scans, or nerve-conduction studies are not likely to yield a definitive diagnosis. They may show structural abnormalities etc., but nothing more. The diagnosis is dependent almost entirely upon epidemiological evidence (seven affected people on the same job) and findings on physical examination (as described above). That said, examination by a Neurologist is still in order.

Now this point is very important: Never again should any of these seven people work near the "glue line." As for the glue lines themselves, my advice is to insure that all vapors are exhausted ***away*** from any workers.

In spite of being forced by circumstances into the role of unwilling informant, I would still like to be of help. If I can be of assistance in any way, do not hesitate to call.

Yours truly,

Ben Wofford, M.D.
CC: OSHA, 4407 Bland Rd., Suite 210, Raleigh, NC 27609. (919) 790-8096/FAX (919) 790-8224

The Clinic for People Without Health Insurance
Ben Wofford, M.D.
105 N. Main Avenue, Newton, NC 28658
(828) 466-2330 Fax (828) 466-2338

January 31, 2005

Royal Comfort
Plant #2
Conover, NC

Re: [redacted]

Dear Sir or Madam:

[redacted] one of your employees, came to see me today because of numbness, weakness in the legs, and unsteadiness (along with other similar and associated symptoms).

Physical Examination disclosed an otherwise unremarkable person who, neurologically, appears to have been exposed to a neurotoxin of some sort. [redacted] does indeed have an unsteady gait, [redacted] reflexes are hyperactive, and [redacted] a positive Rhomberg Test. The rest of the examination was essentially unremarkable.

Close questioning brought out the history [redacted] works [redacted] in an un-ventilated area. [redacted] symptoms become worse as the week progresses, and they tend to clear on week-ends [redacted] is not at work. Closely questioned further, it appears [redacted] is not the only employee with these symptoms - some worse than what [redacted]

It appears [redacted] un-ventilated work area and exposure to [redacted] is responsible [redacted] condition. My suggestion is that the area be well-ventilated; otherwise, serious harm may accrue to [redacted] and your other employees. Please do not hesitate to call on me if I can be of any service in this or any other employee health matter.

Sincerely,

Ben Wofford, M.D.

P.S. [redacted] is by far the most severely affected. [redacted] MUST stay out of the [redacted]

(Rec'd on 4/6/05)

OSHA's Form 300 (Rev. 01/2004)

Log of Work-Related Injuries and Illnesses

Attention: This form contains information relating to employee health and must be used in a manner that protects the confidentiality of employees to the extent possible while the information is being used for occupational safety and health purposes.

Year 2005

U.S. Department of Labor
Occupational Safety and Health Administration
Form approved OMB no. 1218-0176

You must record information about every work-related death and about every work-related injury or illness that involves loss of consciousness, restricted work activity or job transfer, days away from work, or medical treatment beyond first aid. You must also record significant work-related injuries and illnesses that are diagnosed by a physician or licensed health care professional. You must also record work-related injuries and illnesses that meet any of the specific recording criteria listed in 29 CFR Part 1904.8 through 1904.12. Feel free to use two lines for a single case if you need to. You must complete an Injury and Illness Incident Report (OSHA Form 301) or equivalent form for each injury or illness recorded on this form. If you're not sure whether a case is recordable, call your local OSHA office for help.

As of April 6

Establishment name Royale Comfort Seating
City Conover State NC

Identify the person		Describe the case			Classify the case				Enter the number of days the injured or ill worker was:		Check the "Injury" column or choose one type of illness:					
(A) Case no.	(B) Employee's name	(C) Job title (e.g., Welder)	(D) Date of injury or onset of illness	(E) Where the event occurred (e.g., Loading dock north end)	(F) Describe injury or illness, parts of body affected, and object/substance that directly injured or made person ill (e.g., Second degree burns on right forearm from acetylene torch)	(G) Death	(H) Days away from work	(I) Job transfer or restriction	(J) Other recordable cases	(K) Away from work	(L) On job transfer or restriction	(M) Injury (1)	Skin disorder (2)	Respiratory condition (3)	Poisoning (4)	Hearing loss (5)	All other illnesses (6)
			1/31 month/day	glue line	ALEDGED NEUROTOXIN INJURY		✓			65 days	___ days			✓			
			1/31 month/day	glue line	ALEDGED NEUROTOXIN INJURY		✓			65 days	___ days			✓			
			2/8 month/day	glue line	ALEDGED NEUROTOXIN INJURY		✓			57 days	___ days			✓			
			1/31 month/day	glue line	ALEDGED NEUROTOXIN INJURY		✓			65 days	___ days			✓			
			1/31 month/day	glue line	ALEDGED NEUROTOXIN INJURY		✓			65 days	___ days			✓			
			1/31 month/day	glue line	ALEDGED NEUROTOXIN INJURY		✓			65 days	___ days			✓			
			2/7 month/day	glue line	ALEDGED NEUROTOXIN INJURY		✓			58 days	___ days			✓			
			1/31 month/day	glue line	ALEDGED NEUROTOXIN INJURY				✓	___ days	___ days			✓			
			2/21 month/day	glue line	ALEDGED NEUROTOXIN INJURY		✓			44 days	___ days			✓			
			3/11 month/day	SHIPPING	ALEDGED NEUROTOXIN INJURY				✓	___ days	___ days			✓			
			3/14 month/day	Seat Dept.	ALEDGED NEUROTOXIN INJURY				✓	___ days	___ days			✓			
			2/21 month/day	FIBER DEPT.	ALEDGED NEUROTOXIN INJURY				✓	___ days	___ days						
			/ month/day														
					Page totals ▶					484				14			

Be sure to transfer these totals to the Summary page (Form 300A) before you post it.

Page ___ of ___

Public reporting burden for this collection of information is estimated to average 14 minutes per response, including time to review the instructions, search and gather the data needed, and complete and review the collection of information. Persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. If you have any comments about these estimates or any other aspect of this data collection, contact: US Department of Labor, OSHA Office of Statistical Analysis, Room N-3644, 200 Constitution Avenue, NW, Washington, DC 20210. Do not send the completed forms to this office.

As of April 6, 2005 14 wks into yr.

80 ees x 40 hrs/wk = 3200 (1 wk)
manhrs
x 14
11,200 manhrs

4 Changed to "Poison"

MID SOUTH ADHESIVES, INC.

5611 UNIVERSAL DRIVE
MEMPHIS, TENN. 38181
901-795-1943

P. O. BOX 18641
MEMPHIS, TENN. 38181-0641
DEWAYNE HARTSOE, PRESIDENT

February 15, 2005

Attn: [redacted]
Royale Comfort Seating, Inc.
633 4th St. Place S.W.
Conover, NC 28613

Dear [redacted]

Our representative [redacted] ran air grab samples in your factory to determine the concentration of n-propyl bromide in the atmosphere at the time of sampling. Below are the results of the test.

Test Date: February 14, 2005

Apparatus: Gastec Detector Tubes No. 136L and Gastec Pump

Temperature: 50 Deg. F.

Relative Humidity: 97%

Results: The test was taken at shoulder height and 3 feet to the left of [redacted] All produced readings of at least 100 ppm n-propyl bromide (1-bromopropane). This indicates that the concentration of n-propyl bromide in the atmosphere at the time of sampling was equal to or greater than 100 ppm.

It should be noted that Mid South Adhesives strongly recommends that Royale Comfort Seating seriously look at the installation of proper ventilation or the use of proper respiratory protection of their employees to maintain an exposure limit to n-propyl bromide below the TLV of 10 ppm as recommended by ACGIH and as noted on our most recent MSDS. Respiratory programs must be in compliance with NIOSH and in accordance with 29 CFR 1910.134. The above should be noted if Royale Comfort Seating continues with the use of n-propyl bromide based adhesives. Mid South Adhesives will also extend its services in order to assist Royale Comfort Seating in any way it can to reduce employee exposure to n-propyl bromide.

It should also be noted that Mid South Adhesives also manufactures a number of water-based adhesives that will do the same bonding operation as 6464 or n-propyl bromide based adhesives that eliminate the necessity for respiratory protection.

[redacted] I cannot stress enough the need for Royale Comfort seating to either eliminate the use of n-propyl bromide based adhesives such as our 6464, and use a water based type adhesive thus eliminating the exposure of employees to n-propyl bromide or implementing a respiratory protection program that will reduce employee exposure. The test we performed in your factory showed that the concentration of n-propyl bromide in the atmosphere was at least 100 ppm at the time of testing. The exposure level of 10 ppm as recommended by ACGIH is for a time weighted average over 8 hours. With a concentration of 100 ppm in the atmosphere at the time of sampling indicates that your employees are receiving exposure far in excess of 10 ppm TWA.

Should you have questions regarding the test or you would like to discuss options with respect to respirators or ventilation systems, or alternative water-based adhesives, please contact our representative, [redacted] Although we send an MSDS with every shipment of 6464 to your facility, I have also included a copy of our most recent MSDS on 6464 in case you do not have a copy on file.

Sincerely,

Royale Comfort Seating Inc.

February 28, 2005

Mid South
3815 North Main St.
Granite Falls N.C. 28630

Subject: Continued search for non-toxic non-flammable spray adhesive for Royale Comfort Seating #2

Please assist us in finding a non-toxic, non-flammable spray adhesive for Royale Comfort Seating to use in the Cushion production process. In the past we used methylene chloride, which was found to be a cancer suspect agent. We tried to use a water base adhesive, which did not work for us. Now we are using your 6464 and 6474 High solids soft seam adhesive. These adhesives we have learned are neurotoxin. Also the cleaner you provided, 6440 Cleaner is also found to be a neurotoxin. Recently we are experiencing at least [redacted] of our employees being [redacted] by their exposure to this adhesive. All [redacted] experienced [redacted] and [redacted] Also Hyperreflexia, Romberg's Sign and inability [redacted]

To correct this problem we have added fans, required respirators, provided barrier creams, provided training, and are working on installation of a new venting system. Please inform us of any new substitute chemicals that may work for our process.

If you have questions or need additional information feel free to contact us.

Thank you.

P.O. Box 235 • NC Hwy. 16 South • Taylorsville, NC 28681 • Telephone 828-632-2865

[redacted]

Date: 04-01-05 Time: 11:04 AM Interview Place: St. Joseph Church, Newton, NC

Name: [redacted] Phone: [redacted]
Address: [redacted]
City: Newton, [redacted]
Birth date: [redacted]
Employed by: Royale Comfort Seating
Company address: 633 4th St Place SW, Conover, NC 28613
Occupation: Gluer Time in Occupation: [redacted]
Employed from: [redacted] to: date

I hereby depose and say: I started working at Royale Comfort Seating through a staffing company. I am not going to work at this time because the doctor instructed me so, and told me that if I valued my life I should not return to that job. The company insurance is paying me weekly for disability. My function was to glue foams with fiber applying glue with a spray gun. Since I started this work I was never trained in relation to safety at workplace, chemical hazards communication, or material safety data sheets (MSDS). I never had a periodic safety talk. I was never given any kind of personal protection equipment. I arrived at home with contamination in my clothes and my body. I developed symptoms like heat coming out of the body from the waist down, followed by numbness and lack of control of the legs to the point that I could not remain standing and I needed help from others to go to the bathroom. This began to occur about [redacted] I commented this problem to my supervisor [redacted] who paid no attention and never responded. I went to [redacted] and I returned to work on [redacted] I worsened and I went to see the doctor on my own initiative and he instructed me not to return to work because I was intoxicated by the glue. The company sent us to another doctor who is observing us. We are not taking any medicine. [redacted]

Signed: [redacted] Date: 04-01-05

Witness: [redacted]

[redacted]

Date: 04-01-05 Time: 2:12 PM Interview Place: St. Josepn Church, Newton, NC

Name: [redacted] Phone: [redacted]
Address: [redacted]
City: [redacted]
Birth date: [redacted]
Employed by: Royale Comfort Seating
Company address: 633 4th St Place SW, Conover, NC 28613
Occupation: Gluer Time in Occupation: [redacted]
Employed from: [redacted] to: date

I hereby depose and say: Presently I am not going to work by recommendation of Dr. Woodford who forbid me to expose to the glue. I just received payment of insurance. I applied glue to the foams for cushions with a spray gun. I was never trained in topics of safety at workplace, or material safety data sheets (MSDS). I never had safety meetings or safety talks. I was never offered and I was never obliged to wear personal protective equipment. I started feeling dizzy and I lost strength and control of my legs. I went to two hospitals and they did not find anything. When I [redacted] I improved. I returned to work and I worsened again. We found out at work that the symptoms were similar for all workers in the glue line. Finally [redacted] a coworker, sent us to Dr. Woodford who specified that the problem was produced by the toxic glue and forbid me to return to the factory if we appreciated our lives. Now I can only mobilize myself with [redacted]

Signed: [redacted] Date: 04-01-05

Witness: [redacted]

[redacted]

Date: 04-01-05 Time: 11:51 AM Interview Place: St. Joseph Church, Newton, NC

Name: [redacted] Phone: [redacted]
Address: [redacted]
City: Newton, [redacted]
Birth date: [redacted]
Employed by: Royale Comfort Seating
Company address: 633 4th St Place SW, Conover, NC 28613
Occupation: Gluer Time in Occupation: [redacted]
Employed from: [redacted] to: [redacted]
Then [redacted] to: [redacted]

I hereby depose and say: I stopped working since [redacted] per instruction of physician from Newton who free of charge examined me and other employees which were affected at the workplace. I am receiving a weekly compensation. My function was to glue foam for cushions and pillows applying glue with a spray gun. I was never trained in topics of safety at the workplace, or chemical hazards, or personal protection equipment, or material safety data sheets (MSDS). I was never provided personal protection equipment and I was never required to wear it. I started feeling dizzy and with tiredness in the legs. Everything started a week after [redacted] I lost strength in one leg and I could not stay standing. I lost sensation in the leg. Now I cannot remain standing for very long. Cold makes thing worse. The employer knew of this situation because the doctor sent several letters in reference to my case, and the case of other employees which were affected in similar manner. Per instruction of the physician, I stopped working. The company sent me to [redacted]

Signature: [redacted] Date: 04-01-05

Witness: [redacted]

[redacted]

Date: 04-01-05 Time: 1:30 PM Interview Place: St. Joseph Church, Newton, NC

Name: [redacted] Phone: [redacted]
Address: [redacted]
City: [redacted]
Birth date: [redacted]
Employed by: Royale Comfort Seating
Company address: 633 4th St Place SW, Conover, NC 28613
Occupation: Gluer Time in Occupation: [redacted]
Employed from: to: date

I hereby depose and say: I stopped going to work on [redacted] because the physician Dr. Woodford instructed me no to return to the factory. I glued foam and fiber with glue applied by means of a spray gun. I was never trained on safety at workplace, communication of chemical hazards, material safety data sheets (MSDS), or personal protection equipment. I was never required to wear personal protective equipment. I started feeling that my legs were bending and I could not stay standing and I had to support myself on the table in order to be able to work. Then I started with nausea and dizziness. Then I lost the equilibrium from the waist down and I feel my legs numb. I lost coordination with my hands and I was not able to eat given that I could not maintain the silverware in the hand. I was in the hospital on [redacted]. I returned on [redacted] I got several X-ray plates taken in a tunnel and they did not find anything although I continued feeling very bad. Even so I continued going to work. After seeing another physician Dr. Woodford, he forbid me to return to work due to the contamination with the glue. When (before all this) I communicated my situation to the [redacted] never sent me to the doctor. [redacted]

Signature: [redacted] Date: 04-01-05

Witness: [redacted]

Chronological Order of Events

On **October 25, 2004**, a glue line that was located in another area of the plant was moved into the Gluing Department. According to employees, the first people started having symptoms in **November and December of 2004**. They stated that they thought it was because there were more people gluing than previously, resulting in higher concentrations of the glue. Nobody told the employer about the problems they were having because at first, they didn't know why they were having problems. Some employees stated that they didn't know where to find the MSDS, and some knew that they were in the office, but had never asked for one. The first person who went out of work from [redacted] in mid-December, stated [redacted] had no idea that there were other people having the same problems [redacted] was, such as numbness in the legs, dizziness, tingling sensations in the feet and ankles, and back spasms. [redacted] couldn't determine the cause [redacted] illness. [redacted] on **February 7, 2005** because [redacted] afraid [redacted] get fired because [redacted] started talking to some coworkers, they told [redacted] there were others having the same problems. One of the employees gave [redacted] a doctor's name that the other employees were seeing, [redacted] went that afternoon to see Dr. Wofford. He told [redacted] a chemical in [redacted] was causing the problem and recommended [redacted] stay away from [redacted] found out that there were [redacted] who had been missing work because they were having very similar symptoms.

A letter from Dr. Wofford, dated **February 8, 2005**, was received by the Department of Labor, stating his concerns for all of these employees, particularly [redacted] who was walking with the [redacted] from [redacted] exposure. Enclosed in the letter were the doctor's notes about the patients, discussing similar symptoms, including unsteady walking, numbness and tingling in the lower body, and pain in the legs. HCO Sayles spoke to Dr. Wofford on April 13, 2005 and he said that he treats employees without insurance, so he has a lot of [redacted] He believed that is why he had so many of these employees coming to him. Dr. Wofford said that he only did physical exams on these people, no blood work because he does not have a laboratory.

On **February 9, 2005**, a complaint was received about the problems at Royale Comfort Seating, Inc. The complaint inspection was assigned to HCO Cathie Sayles. HCO Sayles attempted to contact [redacted] on Feb. 9, but was not successful. HCO Sayles arrived at the facility on **February 10, 2005** to open the inspection. Upon arrival, [redacted] was aware of the problem of employee exposure to the glue, but wasn't made aware [redacted] received a letter from Dr. Wofford on **January 31, 2005**. Another letter, dated February 7, 2005, was sent to [redacted] explaining Dr. Wofford's concerns about the glue at the plant. Dr. Wofford also faxed a copy of that letter to the U.S. Department of Labor, which was then faxed to NCOSHA. [redacted] told HCO Sayles that after receiving the letter [redacted] began to hear of people going to the doctor and having health problems allegedly due to the glue exposure. [redacted] told HCO Sayles that nobody had even requested an MSDS for the glue. As it was, employees had taken a label from the 55 gallon drum of glue and given it to Dr. Wofford. When HCO Sayles asked employees why they didn't report the symptoms to the employer, they said at first they didn't know what was causing their problems. Later, when they discovered that others had similar problems, they began to think it was from the glue and were afraid of getting fired if they reported it. Instead of reporting this to the employer, all of the [redacted] began calling in sick. [redacted] stated that while people were out of work, they had to hire [redacted] to come and work until these people could come back. There was no respirator program in place at the time. No PPE was required for employees.

HCO Sayles returned to the facility on **February 15, 2005** (2nd onsite visit) to conduct personal air monitoring for exposure to 1-bromopropane, assisted by HCO Russell McCue. At this time, five employees were chosen by the HCOs to represent all of the employees in the area. Employees were chosen because of location. Lab results were received from Analytics Laboratory on **March 2, 2005**. On **March 18, 2005**, a Workplace Measurement Summary was submitted to Royale Comfort Seating, Inc. HCO Sayles faxed the results summary to the facility and told [redacted] to be sure and post it, and to inform employees of the results. While speaking with [redacted] on March

The gluing department is set up in 4 lines of workstation cells. There are approximately 15 employees who work in the area. The locations where employees were working while wearing sampling pumps are shown as shaded ovals in the drawing below (Figure 1). Employees are identified by their initials.

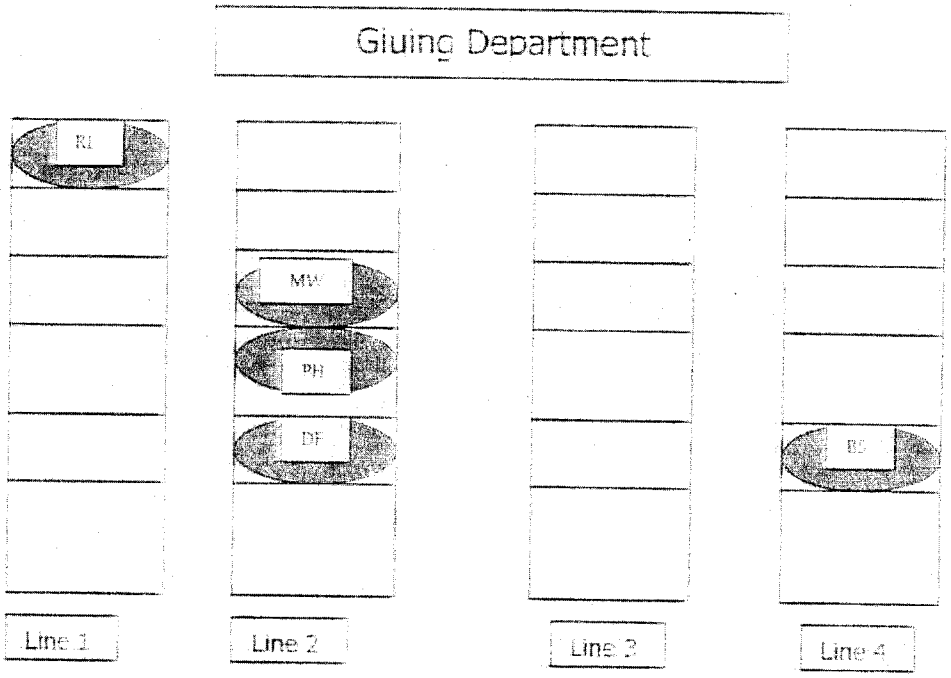


Figure 1. [redacted]

Air samples were collected from five employees. Continuous multiple samples were taken throughout the shift. The results showed that employees working in the inner workstations [redacted] had higher exposures than [redacted] on the end and outer workstations [redacted]. The results were as follows: [redacted] was sampled for a total of 505 minutes, with an eight hour time weighted average (TWA) of 99 ppm; [redacted] was sampled for a total of 578 minutes, with an 8 hour TWA of 137 ppm; [redacted] was sampled for a total of 567 minutes, with an 8 hour TWA of 114 ppm; [redacted] was sampled for a total of 585 minutes, with an 8 hour TWA of 76 ppm; [redacted] was sampled for a total of 587 minutes , with an 8 hour TWA of 52 ppm.

As indicated in the above paragraph, employees on the outer workstations, [redacted] had significantly lower exposures than [redacted]. This is likely due to the location of these employees relative to other workers.

When calculating air sampling concentrations, it is typical to calculate the results based on eight hours (480 minutes). If employees work greater than eight hours, the NC Field Operations Manual Chapter 15, states that the HCO must sample the periods of greatest exposure. In this case, all sampling times were above eight hours, and results were calculated using the samples with the highest concentrations. In some instances, one sample was removed from the calculation as to compare the results to the eight hour recommended guidelines of exposure. If all of the samples had been calculated using 480 minutes, the results would appear higher because nine to ten hours of exposure would be calculated as though employees received these concentrations in only eight hours.

WM. C. REYNOLDS COMPANY, INC.

Proposal

1150 25th Street, SE

MECHANICAL CONTRACTOR

WM. C. REYNOLDS COMPANY, INC.
1150 25TH ST SE
PO BOX 2068
HICKORY NC 28603
(828-324-4540)

P.O. Box 2068 Hickory, NC 28603
Phone (828) 324-4540
Fax (828) 324-0389

ATTN: [redacted]

ROYAL COMFORT	PHONE: 244-7718	DATE: 2-24-05
63 5TH ST PL SW	VENTILATION: PLANT #2	
CONOVER NC 28613		
ARCHITECT:		Job Phone:

WE OFFER THE FOLLOWING QUOTATIONS:

PROPOSAL #1

FURNISH & INSTALL ONE (1) GREENHECK ROOF MOUNTED EXHAUST FAN MODEL TAUB42 RATED AT 19100 CFM @ 1.0" S.P. WITH 7.5 HP MOTOR. ACCESSORIES INCLUDE ROOF CURB, DISCONNECT SWITCH.

FURNISH & INSTALL APPROXIMATELY 80 FT. MAIN SPIRAL DUCTWORK & APPROXIMATELY 120 FT. BRANCH SPIRAL DUCTWORK. CONNECT DUCTWORK TO EIGHT (8) SPRAY BOOTHS.

PRICE: THIRTEEN THOUSAND NINE HUNDRED & EIGHTY SEVEN DOLLARS ($13,987.00)

PROPOSAL #2

FURNISH & INSTALL EIGHT (8) 12" ROUND INLINE FANS & DUCTWORK THRU ROOF FROM SPRAY BOOTHS. FANS RATED AT 1905 CFM @ .75" SP, 3/4 HP MOTOR

PRICE: TEN THOUSAND EIGHT HUNDRED & EIGHTEEN DOLLARS ($10,818.00)

NOT INCLUDED IN PROPOSAL:

1. ROOFING
2. ELECTRICAL WIRING
3. DISCONNECT SWITCHES FOR FANS IN PROPOSAL #2

ALL MATERIAL IS GUARANTEED TO BE AS SPECIFIED & COMPLETED IN WORKMANLIKE manner according to standard practice. Any alteration or deviation from the above specifications involving extra costs will be executed only upon written orders, and will become an extra charge over and above the estimate. All agreements contingent upon strikes, accidents or delays beyond our control. Owner to carry fire, tornado and other necessary insurance. Our workers are fully covered by workmans compensation insurance.

Authorized Signature: [redacted]

Acceptance of Proposal: The above prices, specifications and conditions are satisfactory and are hereby accepted. You are authorized to do the work as specified. Payment will be made as outlined above.

Signature: _____

Date of Acceptance: _____ Signature: _____

OSHA Compliance Outline

January 31, Notification from Dr. Ben Wofford First notice of exposure
Wed. February 9, 2005 OSHA complaint inspection
February 11, 4 Respirators and Cartridge brdered
February 11, ordered motor for fan
February 14, ordered respirator and cartridge
February 14, [redacted] sampled for n-propyl bromide 100 ppm at time of testing (10 ppm TLV)
February 14, [redacted] Tested employees for use of respirators. Annette Price and Deborah Lackey restricted from Glue Area temporarily
February 14, ordered lockout/tagout padlock and larger fan motor
February 15 Fans turned on and glue use turned down at guns installed larger motors on fans
February 16, 8 employees cleared for respirators, 4 cleared for respirators but had symptoms, 2 employees found to be claustrophobic, Darliine Foust needs silicon latex respirator
February 24 Requested quote for ventilation system Wm. C Reynolds
February 28, Cleaned Glue Booths and under conveyor belt Requested Mid-South to continue to search for non-toxic, non-flammable spray adhesive, provided nitrile gloves to employees
February 28 ordered Disp. respirators
March 2, added floor fans to glue line
March 3 ordered Butyl Glove for test Ordered nitrile gloves for Glue line employees
March 4, Training updated for Glue Line Employee for respirators and safety orientation review.
March 5, Ordered respirator
March 7, Provide facility inspection Hazard Assessment with report of "OSHA Compliance Suggestions to be completed.
March 8, ordered respirators, cartridges, and nitrile gloves
March 10, Training updated for Remaining Plant Employees on safety orientation.including; Hazard Communication, Workers Compensation Requirements, Personal Protective Equipment, Emergency Response, Lockout/Tagout, Bloodborne Pathogens, Fire Extinguisher Use. Tested

Waterbased Flex Foam Glue

March 14, Decision to Move Glue Line Booths closer to wall fans immediately so air will flow more effectively.

ROYALE

COMFORT

SEATING, INC.

ORIENTATION

WELCOME TO THE TEAM!

TABLE OF CONTENT

INTRODUCTION

[redacted]

INSURANCE QUESTIONS
ACCIDENTS OR INJURIES(FIRST, PLEASE NOTIFY YOUR IMMEDIATE SUPERVISOR OR PLANT MANAGER. THEY WILL NEED TO BE AWARE AND CAN ADVISE FURTHER INSTRUCTION).

..... [redacted]

PAYROLL QUESTIONS..... [redacted]

LOCATION OF ALL IMPORTANT INFORMATION

MSDS (MATERIAL SAFETY DATA SHEETS)
LOCATION: FRONT OFFICE..... [redacted]

INSURANCE, AFLAC, SAVING PLAN AND ANY OTHER CHANGES OR GENERAL INFORMATION, WILL BE POSTED IN THE PLANT FOR YOU INFORMATION.

A FULL - TIME EMPLOYEE MUST BE AVAILABLE TO WORK 40 HRS PER WEEK AS FOLLOWS:

MONDAY - THURSDAY 7:00AM - 4:30PM
FRIDAY 7:00AM - 11:00AM

THERE IS A 30 MINUTE LUNCH STAGGERED, BEGINNING AT 11:45AM. ALSO TWO (2) 10 MINUTE BREAKS AT 9:30AM AND 2:30PM. YOU ARE REQUIRED TO PUNCH IN AND OUT AT LUNCH REGARDLESS OF WHETHER OR NOT YOU LEAVE THE PREMISES.

VACATION

YOU MUST BE A FULL - TIME EMPLOYEE TO RECEIVE ANY BENEFITS. **AFTER 3 MONTHS OF CONTINUOUS SERVICE** EACH EMPLOYEE IS ENTITLED TO RECEIVE 8 HOURS PAY FOR THE FOLLOWING:

1. GOOD FRIDAY
2. LABOR DAY
3. FRIDAY AFTER THANKSGIVING

AFTER INITIAL 6 MONTHS OF CONTINUOUS SERVICE
ONE FULL WEEK OF PAID VACATION--TAKEN EITHER AT 4TH OF JULY OR CHRISTMAS. WHICHEVER IS CLOSES AFTER 6 MONTHS.
AFTER ONE FULL YEAR OF CONTAINERS SERVICE
2ND FULL WEEK OF PAID VACATION *** BIRTHDAY OFF WITH PAY
AFTER 10 YEARS OF CONTINUOUS SERVICE *** 3RD WEEK PAID VACATION
TO RECEIVE PAY FOR ANY SINGLE HOLIDAY OR VACATION WEEK, EMPLOYEES MUST WORK THE DAY BEFORE AND THE DAY AFTER THE HOLIDAY.

BENEFITS

HEALTH INSURANCE CARRIER IS ..... UNICARE
SUPPLEMENTAL INSURANCE ..... AFLAC
SAVING PLAN ..... FIRST UNION
INSURANCE AND SAVING PLAN ARE AVAILABLE ONLY AFTER 60 DAYS OF CONTINUOUS EMPLOYMENT

ATTENDANCE POLICY

ONE (1) ABSENCE OR THREE (3) TARDIES IN A ONE (1) MONTH PERIOD. IF UNABLE TO WORK ON A SCHEDULED WORKDAY OR IF GOING TO BE TARDY, **EACH EMPLOYEE IS REQUIRED TO CALL IN AND TALK DIRECTLY TO THEIR SUPERVISOR OR PLANT MANAGER BY 7:30AM.** THE SUPERVISOR AND/OR PLANT MANAGER ARE RESPONSIBLE FOR DECIDING IF THE ABSENCE OR TARDY IS TO BE EXCUSED. EACH EMPLOYEE IS RESPONSIBLE FOR THEIR OWN WAY TO AND FROM WORK. TRANSPORTATION IS NOT AN ACCEPTABLE EXCUSE.

THE FIRST 60 DAYS OF EMPLOYMENT ARE CONSIDERED A PROBATION PERIOD. DURING THIS TIME, YOU ARE EVALUATED ON PERFORMANCE, ATTENDANCE, AND THE ABILITY TO WORK WITH OTHERS. THE EMPLOYEE AND/OR ROYALE COMFORT SEATING, RESERVES THE RIGHT TO TERMINATE EMPLOYMENT FOR ANY REASON DURING THE 60 DAY PROBATIONARY PERIOD OR THEREAFTER.

M S D S

MATERIAL SAFETY DATA SHEETS

****

ROYALE COMFORT SEATING has developed a HAZARD COMMUNICATION STANDARD in our faculty to reduce the occurrence of workplace illnesses and injuries caused by hazardous chemicals. This standard is designed to provide information for all new and existing employees of the company.

Depending on which area of the plant you will be working, you will most likely be working with or around some type of chemical. We have a written plan for all chemicals at this plant. Each chemicals is listed on a MSDS (Material Safety Data Sheet) and all information about these chemicals are found on these sheets as well as first aid for exposure, side effects of exposure, adverse reactions of exposure and protective equipment you can wear to prevent illness or injury.

The MSDS Book ~~are~~ is located in the front office for your inspection at any time during your employment.

You may or may not work with these chemicals, but you should be aware of their existence in our plant. You should also know some of the adverse reactions to the chemicals that you will be working around.

YOUR SUPERVISOR WILL BE RESPONSIBLE FOR PROVIDING PROPER PPE (PERSONAL PROTECTIVE EQUIPMENT) FOR YOU. IF AT ANY TIME, YOU FEEL THAT YOU ARE FEELING SICK OR FAINT, NOTIFY YOU SUPERVISOR IMMEDIATELY.

THE FOLLOWING LIST OF CHEMICALS ARE USED IN THIS PLANT.

ADHESIVE ..... used at the glue line. The glue gives off vapor when spraying. If the vapors bother you, masks are available for you protection at no cost. It is recommendation tat you wear the mask when working in the spray area. If you get the glue in you eyes, seek help immediately. If you develop a headache, feel dizzy and/or nauseated, notify your supervisor immediately. If you accidentally ingest this chemical please contact your supervisor.

THINNER/CLEANER ..... used at glue line. This product is used to thin glue or clean glue from an abject. Inhalation of vapors or mist can cause headaches, nausea, irritation of the nose, throat and lungs. It is recommended that you wear a mask when using this product. When splashed on skin, may cause mild irritation, was immediately. If you accidentally ingest this product or get in eyes, contact your supervisor immediately.

SPRAY SILICONE ..... used in several areas of the plant. Sewing machine operators use this product to keep their sewing area, (needle and table) slick for ease of sewing material. Cutters use it to aciculate cutting. Cushion stuffers this spray to make stuffing seats smoother. May cause dizziness in high concentration. If symptoms appear contact supervisors immediately. No smoking in or around this chemical.

SPRAY ADHESIVE ..... used by glue area or cushion stuffer to make small repair in cushion. High vapor content may cause dizziness or irritation of skin. Avoid contact with skin and eyes. Flush area immediately with water. No smoking in or around area where this chemical is being used or stored.

C-60 SOLVENT ..... used in seat, shipping departments and other areas where stains appear on cushions. This chemical may cause some irritation to the mucous membranes or skin. It may also cause drying of the skin. Always wash the skin immediately after contact with soap and water. If accidentally splashed or sprayed in eyes, flush with water immediately. Avoid breathing vapors, mask are provided if needed.

INK ..... used by cutters to mark style numbers on material. Prolong breathing of vapors may cause headache or dizziness. Notify supervisor if any symptoms appear.

FIBER ..... the polyester fiber has no know physical or health hazards associated with it. However, exposure to chemical substances may occur as a result of processing these fibers. Mask should be worn when blowing the fiber into bags. The polymer fiber will burn if exposed to flame. No smoking in or around area where fiber is being used or stored.

GOJO ..... a glycerin base hand cleaner. Should pose no health problems to user. If irritation does occur with use, discontinue using this product. Should avoid splashing or rubbing in to eyes. If eye exposure does occur, flush immediately.

PROVON SKIN MOISTURIZER WITE ALOE AND VITAMINS ..... is a hand cream used to protect your skin from irritation when working around fibers and fabrics. There should be no adverse reaction, except for mild irritation. If irritation does occur, discontinue use.

These are the chemicals present in our plant. If you will be working in or around any of the above mentioned areas you may want to read more information. The MSDS are located in the front office for your inspection at any time during your employment.

BLOODBORNE PATHOGENS

Royale Comfort Seating, Inc., has a strict policy regarding the handling of human blood or body fluids.

If you witness a co-worker or friend that has had a injury in the plant, you are not to handle any of the blood or touch any surface that blood may tainted. There are certain viruses in some human blood that can cause a serious illness. These viruses or micro-organisms are called bloodborne pathogens. They arrive their name from the fact that they are spread through direct blood contact from a person that has a bloodborne illness such as HBV (Hepatitis B or C) or HIV (Human Immunodeficiency) AIDS.

There is no way you can tell if a person might have an illness, so treat all blood as if it might be contagious.

Should you see any surface that has blood or blood stain you should contact your supervisor immediately. It is not your responsibility to clean it up, but it is your responsibility to report it. We have people trained to handle all injuries and blood clean up.

ALWAYS NOTIFY YOU SUPERVISOR IF YOU WITNESS AN ACCIDENT OR HAVE AN ACCIDENT!

If you have any questions or concerns regarding BBP in the workplace, Royale Comfort Seating, Inc. has an BBP Exposure Control Plan located in the front office that will explain or answer your questions. Please feel free to read it at any time.

FIRE SAFETY

Royale Comfort Seating has a fire evacuation policy that will be explained to you at this time.

In the event of a fire, the building will be evacuated. The alarm will sound and you will exit the that will be assigned to you. Each department has an assigned door in which to exit. You will also have an alternate door should the fire be in the area of your assigned door.

Once you are outside the building, you will have a gathering area for you department. Each department has a different area to meet. This is very important that you adhere to this rule. You must be accounted for by your supervisor as soon as the is emptied. If you are not in your group and can not be found, someone will have to look for you.

If for some reason you are in another area of the plant when the alarm sounds you should exit at the nearest door and continue to your own gathering area. When you tour the plant, your supervisor should point these doors out to you and explain the gathering procedure. If you supervisor fails to identify these areas, please remind them to do so. These are very important facts you should be aware of.

LOCK-OUT/TAG-OUT POLICY

Royale Comfort Seating has established a policy and procedure regarding a machine or piece of equipment that needs to be serviced or repaired.

Maintenance personnel will place a lock-out/tag-out tag on the machine. This tag will remain until it has been repaired or serviced. Employees are not to use the machine or piece of equipment until maintenance has removed the tag and established the equipment in working order.

NC Department of Labor
Division of Occupational Safety and Health

Inspection Number: 125307686
Inspection Dates: 01/23/96 - 01/24/96
Issuance Date: 02/23/96

Citation and Notification of Penalty

Company Name: Royale Comfort Seating, Inc.
Inspection Site: Hwy. 16 S., Taylorsville, NC 28681

Citation 2 Item 9 Type of Violation: Nonserious

29 CFR 1910.1200(h): Employees were not provided information and training as specified in 29 CFR 1910.1200 (h)(1) and (2) on hazardous chemicals in their work area at the time of their initial assignment and whenever a new hazard was introduced into their work area:

a) facility-for the employees who are exposed to potentially hazardous chemicals in the foam department.

Date By Which Violation Must be Abated: 03/27/96
Proposed Penalty: $ 0.00

for CHARLES N. JEFFRESS
Director

25×10 32×10

State of North Carolina
Department of Labor
Division of Occupational Safety & Health

WORKPLACE MEASUREMENT SUMMARY

Cherie K. Berry
Commissioner

John H. Johnson
Deputy Commissioner/OSH Director

Company: Royale Comfort Seating, Inc.
Address: P.O. Box 235, Taylorsville, NC 28681-0235
Sampling date(s): 01/31/2002
Compliance Officer: Pat O'Brien
OSHA IMIS No.: 305088643

During a recent compliance inspection, employee exposure monitoring was performed for potential workplace hazards. All personal and/or area sampling data was obtained with pre- and postcalibrated equipment used in accordance with professional industrial hygiene practice. The exposure measurements are summarized below.

Employee/Oper. Sampled	Hazard Sampled	Exposure Level	Permissible Exposure Limit (PEL)
[redacted]/Glue Line	1-bromopropane	245 ppm	*100 ppm
[redacted] Glue Line	1-bromopropane	130 ppm	*100 ppm
[redacted] Glue Line	1-bromopropane	83.9 ppm	*100 ppm

This record must be maintained in accordance with 29 CFR 1910.1020 (Access to Employee Exposure and Medical Records).

*OSHA, at this time, does not have a permissible exposure limit (PEL) for 1-bromopropane. The exposure limit listed in the PEL column is the manufacturer's recommended exposure limit. If and when OSHA does enforce a PEL for 1-bromopropane, it may be lower than the manufacturer's recommended limit of 100 ppm.

ppm - parts of contaminant per million parts of air.

cc: Case file.

Copy

CHERIE K. BERRY
COMMISSIONER

TIM CHILDERS
WEST COMPLIANCE BUREAU CHIEF
DIVISION OF OCCUPATIONAL SAFETY AND HEALTH

Februawry 25, 2002

[redacted]

RE: OSH Inspection 305088643
OSH Complaint 203507868

[redacted]

Following your complaint, a health compliance officer from the Bureau of Compliance, Division of Occupational Safety and Health conducted an inspection of Royale Comfort Seating, Inc. in Taylorsville, NC on 01/31/2002.

Enclosed are copies of citations resulting from the inspection. Your compiaint (itemized and underlined) is restated below, followed by our findings.

1. Employees have not received their hazard communication training to include the location of the MSDS book and chemical training such as glue. As a result, employees have no knowledge of symptoms of overexposure.

   Substantiated. Employee interviews revealed that some employees who worked on the glue line had not received the required hazard communication training. A citation was issued for this item.

2. The employer does not require the use of respirators and only makes available upon request. Employees are given only paper masks that are ineffective against the fumes created by spraying glue.

   Substantiated. The review of the material safety data sheet (MSDS) for the adhesive used on the glue line revealed that the adhesive did not contain any chemicals for which the North Carolina Division of Occupational Safety and Health (NCOSH) enforced a permissible exposure limit (PEL). The primary ingredient of the glue was 1-Bromopropane. The manufacturer's recommended exposure limit was 100 ppm, according to the MSDS.

901 PETERS CREEK PARKWAY • WINSTON-SALEM, NORTH CAROLINA 27103-4551
(336) 761-2700 • FAX (336) 761-2326

Copy

Since the health compliance officer (HCO) had no established exposure limit to enforce, the HCO decided to do air sampling to show the employer how the exposure level in their facility compared to the manufacturer's recommended exposure limit. The results of the air sampling showed that 2 of the 3 sampled employees were exposed to 1-Bromopropane at levels above the manufacturer's recommended exposure limit. Three fans were installed in the wall adjacent to the glue line to provide dilution ventilation. The HCO recommended that the employer install local exhaust ventilation at each of the 9 booths on the glue line.

As a result of the lack of enforceable exposure limits, the employer was not required to make employees use respirators. The HCO recommended to the employer that they keep National Institute for Occupational Safety and Health (NIOSH) approved respirators for organic vapors available for employees who wanted to use them. No citations were issued for this item.

3. There is poor ventilation in the glue line area. As a result, employees are suffering from nausea and dizziness.

Partially substantiated. The review of the MSDS for the adhesive used on the glue line revealed that the adhesive did not contain any chemicals for which NCOSH enforced a PEL. The primary ingredient of the glue was 1-Bromopropane. The manufacturer's recommended exposure limit was 100 ppm, according to the MSDS.

Since the HCO had no established exposure limit to enforce, the HCO decided to do air sampling to show the employer how the exposure level in their facility compared to the manufacturer's recommended exposure limit. The results of the air sampling showed that 2 of the 3 sampled employees were exposed to 1-Bromopropane at levels above the manufacturer's recommended exposure limit. Three fans were installed in the wall adjacent to the glue line to provide dilution ventilation. The HCO recommended that the employer install local exhaust ventilation at each of the 9 booths on the glue line.

The interviews of employees did show that some of the employees had felt symptoms such as dizziness, nausea, and headaches. However, since the HCO did not have an enforceable exposure limit for the adhesive, the HCO was not able to require the employer to implement engineering controls, such as increased ventilation. No citations were issued for this item.

If you do not agree with our investigation results, you may seek further clarification from the District Supervisor or Bureau Chief. If dissatisfaction with the determination still remains after further conversation with the District Supervisor or Bureau Chief, you also have the right to an informal review by the Director's Office. A review may be obtained by submitting a written statement of your position to the Director's Office at the following address:

CDF

4. Date/Time
05/10/11 / 4:30 pm

20. Instance Description - Describe the following:

A) Hazards-Operation/Condition-Accident: Chemical exposure to 1-Bromopropane due to failure to implement adequate engineering controls to minimize exposure levels.

During the inspection, the CSHO determined that the employees were utilizing Spectrum Adhesives 6464 Soft Seam Adhesive, which contains 60-70% 1-Bromopropane. Sixteen employees utilized the adhesive in the Glue Department. The glue was being piped from a 55-gallon drum to their workstations where it is subsequently sprayed from an atomizing gun and applied to cushion foam.

The glue stations were approximately 8 feet wide and 4 feet in depth (as measured away from the employee). The workstations were open. A local exhaust ventilation system was in place, consisting of ductwork that was attached to a hood at each workstation. The hood at each workstation was the width of the workstation and came down to the work table. The employees put a piece of batting over the opening of the hood to help lower the amount of adhesive that gets sucked up into the ventilation system. This batting is only replaced once a day. Employees laid foam pieces on top of the work table and sprayed the adhesive on the foam.

On May 10, 2011, full shift personal air sampling was conducted to analyze the employees' exposure level to 1-Bromopropane. Five of the 16 employees who were working with the chemical were sampled. All five employees sampled were found to have exposure levels exceeding the US Environmental Protection Agency's proposed exposure level of 25 parts per million (ppm). The air sampling results were 62.67 ppm, 86.23 ppm, 67.49 ppm. 77.23 ppm, and 64.87 ppm based on an 8 hour Time Weighted Average. Reference Field Sampling Sheets #43845763, #435845771, #435845789, #435845797, and #435845805, the Workplace Measurement Summary, and Appendix #1.

General Duty Clause Evaluation:

1. **Employer failed to keep the workplace free of a hazard to which employees of that employer were exposed:** All five of the Gluers sampled were employees of Royale Comfort Seating. The employees' average exposure levels were 62.67 ppm, 86.23 ppm, 67.49 ppm, 77.23 ppm, and 64.87 ppm. The employer did not provide the employees with the proper personal protective equipment for the job.

2. **The hazard was recognized in the industry:** The hazards of 1-Bromopropane are discussed on the MSDS. NCDOL has also published a Hazard Alert for 1-Bromopropane which is posted on the safety of the American Home Furnishing Alliance (http://www.ahfa.us/focus/safety.asp#documents). The American Conference of Governmental Industrial Hygienists has proposed an 8 hour Threshold Limit Value of 10 parts per million, and the US Environmental Protection Agency has proposed an exposure limit of 25 parts per million.

3. **The hazard was causing or was likely to cause death or serious physical harm:** Research shows that 1-Bromopropane causes serious central nervous damage in laboratory animals and humans as well. Numerous studies indicated serious CNS symptoms are likely to occur after exposure, including numbness and tingling in the feet and legs with difficulty walking, and various other CNS injuries as well. The National Institute of Occupational Safety and Health (NIOSH) conducted a Health Hazard Evaluation at STN Cushion Company, HETA #2000-0410-2891, located in Thomasville, North Carolina, during 2000-2001. This evaluation documented that employees exposed to 1-Bromopropane experienced dizziness and blurred vision.

NIOSH concluded that properly installed ventilation systems could be used to control exposure to the hazard.

4. **There was a feasible and useful method to correct the hazard:** Abatement methods include revision of the local exhaust ventilation system to improve flow rates and capture velocities, and/or substitution of the chemical with one that does not contain 1-Bromopropane.

B) Equipment: Spectrum Adhesive 6464 Soft Seam Adhesive.

C) Location: Glue Department.

D) Injury/Illness: Central Nervous System damage, reproductive system damage, adverse effects to the liver, kidneys, urinary system, and bone marrow.

E) Measurements: Employer and employee interviews, personal air sampling, and records review.

21. Photo Number	Location on Video
#2, #3, #4, #6, #8, #9, #10, #11, and #12	

23. Employer Knowledge: The employer was aware that the employees were utilizing Spectrum Adhesives 6464 Soft Seam Adhesives. The drums had labels which indicated the contents of the mixture with the principal ingredient listed as N-Propyl Bromide (1-Bromopropane). The employer also provided to the CSHO the Material Safety Data Sheets from the manufacturer which indicated the contents of the 6464 Soft Seam Adhesive and made them apparent to the employer.

24. Comments (Employer, Employee, Closing Conference): [redacted] stated during the closing conference that the company would have someone to come and check the ventilation system and have it cleaned.

25. Other Employer Information:

26. Classification:				
Serious	Knowledge	S or O	Repeat?	Willful?
Y	Y	S	N	N

First Repeat	Second Repeat	Repeat Penalty
NA	NA	NA

Severity and Probability Assessment:

Severity	High	Medium	Low	Non Serious			
	X					Probability	Rating
Probability	# of Employees (1-8)	Frequency (1-8)	Proximity (1-8)	Other Factors (1, 8, or N/A)	Total / # of Factors	Lesser (1.0-4.5)	Greater (4.6-8.0)

Rating	8	7	6	1	22 / 4		5.5

Probability: Greater Probability/ The probability that an injury or illness would occur is judged to be greater. There were 16 employees exposed for 6-7 hrs/day. The proximity is 1-2 ft. The mitigating factors are that the employer has a hazard communication program and maintains the required Material Safety Data Sheets.

Event Date	Event Code	Action Code	Citation Type	Penalty	Abate Date	Final Order
	Z Add transaction	**A Add**	**S Serious**	**3500.00**		

Beverly Stone
Health Compliance Officer II
Occupational safety and Health Division
901 Blairhill Road, Suite 200
Charlotte, N.C. 28217-1578

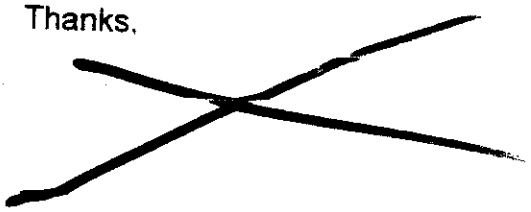
June 1, 2011

Dear Ms. Stone,

As a result of your visit to Royale Comfort Seating on May 10, we have had a local Heating and Cooling Company come to service all the venting system for our plant. They found that there was quite a lot of build up on the fan blades. The mesh wire was found to have a significant amount of buildup also and that was also cleaned. We have pictures of the buildup on the fans and on the wire mesh for you to see. We were informed by the Heating and Cooling Company that three of the fan belts were slipping some. Repairs were made on the fans with loose belts and all booths were cleaned and a program of Booth Cleaning and inspection was installed to make sure booths were cleaned and belts checked on a regular basis. The Fabric Filters also will be changed twice a day instead of once a day to promote efficent air flow through the booths. On June 6 we talked to all sprayers about making sure they spray into the booth area and asked for their ideas on improvements for the booth areas. We actually got two ideas one to add a section to the top of the booth, and another to use cardboard to extend the side of some booths. We are presently closing off the ventilation on booths not being used. It helps with air conditioning and increases suction on

the used booth where they share the same fan. Thank you for your assistance with our safety program here at Royal Comfort Seating.

Thanks,



Citation and Notification of Penalty

Company Name: Royale Comfort Seating
Inspection Site: 140 Alspaugh Dam Rd., Taylorsville, NC 28681

Citation 1 Item 1b Type of Violation: Serious

29 CFR 1910.94(c)(6)(i): The velocity of air into all openings of spray booth(s) without adequate replacement system(s) was less than that specified in Table G10 of subpart G of 29 CFR part 1910 for the operating conditions specified:

a) for the local exhaust ventilation system, which is utilized during the spraying operation in the glue department. The air velocity for the ventilation was measured with an Alnor Thermoanemometer to be approximately 10-30 feet per minute (fpm), on May 10, 2011. This flow rate is well below the required air flow rate of 75-125 fpm, which is specified in Table G10.

Date By Which Violation Must be Abated: 08/23/2011

Citation 1 Item 1c Type of Violation: Serious

29 CFR 1910.134(d)(1)(i): The employer did not select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker was exposed and workplace and user factors that affected respirator performance and reliability:

a) for 1-bromopropane. The gluers in the glue department were spraying Spectrum Adhesives 6464 Soft Seam Adhesive in the manufacture of foam cushions for the furniture industry. The 6464 Soft Seam Adhesive contains 1-bromopropane. On 05/10/11, five of the Gluers were sampled for 1-bromopropane and were exposed to an 8 hour Time Weight Average concentration of 62.67 ppm, 86.23 ppm, 67.49 ppm, 77.23 ppm, and 64.87 ppm, which are well above the US Environmental Protection Agency's proposed exposure limit of 25 ppm. The employer had provided 3M 9210 N95 dust masks to the employees to wear on a voluntary basis. Dust masks are not the appropriate respirator to protect for organic vapors such as 1-bromopropane.

Date By Which Violation Must be Abated: 08/23/2011

NC Department of La r
Division of Occupational Safety ..id Health

Notice of Alleged Safety or Health Hazards

Wed Apr 13, 2011 12:09pm

		Complaint Number		207885708
Establishment Name	Royale Comfort Seating			
Site Address	140 Alspaugh Dam Rd., Taylorsville, NC 28681			
	Site Phone (828) 632-2865		Site FAX	(828) 632-7067
Mailing Address	140 Alspaugh Dam Rd., Taylorsville, NC 28681			
	Mail Phone (828) 632-2865		Mail FAX	(828) 632-7067
Management Official			Telephone	
Type of Business	Cushion manufacturer		Ownership	
Primary SIC	2392	Primary NAICS		314129

HAZARD DESCRIPTION/LOCATION. Describe briefly the hazard(s) which you believe exist. Include the approximate number of employees exposed to or threatened by each hazard. Specify the particular building or worksite where the alleged violation exists.

DESCRIPTION:

1. Employees are concerned about being exposed to various adhesives and silicone spray that are being used in the manufacturing process.
2. Employees are not provided with respiratory protection or gloves when spraying various adhesives.
3. Material safety data sheets for hazardous chemical products, such as adhesives, are not available to employees.
4. One of the sinks in the women's restroom came off the wall and is not operational.

LOCATION:

At facility.

North Carolina Department of Labor
Division of Occupational Safety and Health
901 Blairhill Road, Suite 200
Charlotte, NC 28217
(704) 665-4341 – phone
(704) 665-4342 – fax

WORKPLACE MEASUREMENT SUMMARY

COMPANY: **Royale Comfort Seating**

SITE ADDRESS: **140 Alspaugh Dam Rd., Taylorsville, NC 28681**

INSPECTION DATE(S): **May 10, 2011**

COMPLIANCE OFFICER: **Beverly A. Stone**

REPORT NUMBER: **315638304**

During a recent North Carolina Occupational Safety and Health Compliance inspection, employee exposure monitoring was performed for potential workplace hazards. All personal and/or area sampling data was obtained with pre- and post calibrated equipment used in accordance with professional industrial hygiene practice. The exposure measurements are summarized below.

The scope of the sampling episode was limited to the activity in the work environment on the day of sampling. Although an effort was made to ensure sampling was conducted on a typical workday, the sampling data may not be representative of exposures on subsequent sampling due to changes in production, work practice, equipment, or other factors. The data should not be used to predict exposures in the future in lieu of collection of additional monitoring data to determine compliance after changes are made to the work environment.

Employee/Operation Sampled	Analytes (Hazard Sampled)	Time	Exposure Level	Action Level (1), Permissible Exposure Limit (2), Ceiling (3), STEL (4)
X	1-bromopropane	503 mins.	62.67 ppm	25 ppm
	1-bromopropane	503 mins.	86.23 ppm	25 ppm
	1-bromopropane	503 mins.	67.49 ppm	25 ppm
	1-bromopropane	466 mins.	77.23 ppm	25 ppm
	1-bromopropane	503 mins.	64.87 ppm	25 ppm

It is the responsibility of the employer to inform affected employees of their rights to access their medical and exposure records, including these specific results. This record must be maintained in accordance with 29 CFR 1910.1020 (Access to Employee Exposure and Medical Records).

min = minutes
mg/m^3 = milligrams of contaminant per cubic meter of air
ppm = parts of contaminant per million parts of air

Draft

BOARD OF COMMISSIONERS **ALEXANDER COUNTY**
REGULAR MEETING September 26, 2005 **STATE OF NORTH CAROLINA**

PRESENT: William L. Hammer, Chairman
W. Darrell Robertson, Vice-Chairman
W. Norris Keever
Larry Yoder

ABSENT: Wesley E. Bolick

STAFF: Rick French, County Manager
Jamie Starnes, Clerk to the Board

MEDIA: Gary Herman, The Taylorsville Times

The Alexander County Board of Commissioners held a regular meeting on Monday, September 26, 2005 in the Catawba Valley Community College / Alexander Center Multipurpose Room, Taylorsville, North Carolina.

CALL TO ORDER

Chairman Hammer called the meeting to order at 6:00 PM.

INVOCATION & PLEDGE OF ALLEGIANCE

Commissioner Robertson gave the invocation and also led the Pledge of Allegiance to the Flag.

COMMISSIONER'S REPORT

Commissioner Keever discussed the final meeting of the North Carolina Association of County Commissioners (NCACC) Long Range Planning Committee which he attended on Thursday, September 22, 2005. He pointed out the committee had developed suggestions and goals that would be reviewed by the NCACC Executive Committee and staff and issued to all county commissioners. He also stated that a new executive director has been hired.

Chairman Hammer stated that Commissioner Bolick would not be present at the meeting because his sister-in-law was very ill and he was spending time with her and other family members.

ADOPTION OF AGENDA

Commissioner Keever made a motion to adopt the agenda as presented. Commissioner Robertson seconded the motion. The Board voted unanimously in favor of the motion.

PUBLIC HEARING: N.C. DEPARTMENT OF TRANSPORTATION 2005-2006 SECONDARY ROAD IMPROVEMENT PROGRAM

Clay Lunsford, Division 12 District II Engineer, presented the 2005-2006 Secondary Road Construction Program for Alexander County. He also introduced Mike Holder, Division 12 Engineer, and Reuben Chandler, Division 12 Maintenance Engineer.

Mr. Lunsford discussed the 2005-2006 Secondary Road Construction Program and allocations, which included the following information:

*** FY 2005-2005 Anticipated Allocation:**

Highway Fund - $1,290,833.73
Trust Fund - $1,231,408.27
Total - $2,522,242.00

*** Rural Paving Priority:**

Priority No.	SR No.	Length (Miles)	Road Name & Description	Est. Cost
1F	SR1631	2.10	Stikeleather Road (additional funding) from SR1630 to SR1617	$470,000
2F	SR1309	0.60	Boone Gap Road (additional funding) from SR1310 to dead end	$190,000
3F	SR1548	0.62	Calvin Johnson Road from SR1404 to dead end	$120,000
4F	SR1547	0.50	Joe Barnes Lane from SR1419 to dead end	$140,000
5F	SR1471	0.70	Robertson Road from SR1472 to SR1469	$100,000
6F	SR1619	1.10	Matheson Road from SR1605 to SR1630	$350,000
7F	SR1335	0.80	Russell Gap Road from SR1335 to county line	$195,000
8F	SR1518	0.70	Keever Lane from SR1496 to dead end	$170,000
P.O.P.	SR1492	0.50	Duncan Lane from SR1491 to dead end	$205,000
Total Miles: 7.62			**Subtotal: $1,940,000**	

*** Rural Paving Alternatives:**

Priority No.	SR No.	Length (Miles)	Road Name & Description	Est. Cost
9F	SR1504	0.54	Lackey Road from SR1503 to SR1001	$130,000

*** Subdivision Paving Priority:**

Priority No.	SR No.	Length (Miles)	Road Name & Description	Est. Cost
1F	SR1364	0.10	Renee's Rocky Top Drive (Houch Mountain) from SR1300 to dead end	$25,000
2F	SR1449	0.10	Fox Mountain Road from SR1449 to Iredell County line	$40,000
3F	SR1532	0.34	Winterhaven Road from SR1532 E.O.P. to dead end	$50,000
4F	SR1583	0.34	Haven Circle from SR1582 to dead end	$80,000
Total Miles: 0.88			**Subtotal: $195,000**	

*** Various Spot Stabilization and Secondary Maintenance Subtotal -** $250,175

*** Funds reserved for surveying, right of way acquisition, road additions, contingencies, overdrafts, and paving entrances to certified fire departments, rescue squads, etc. subtotal -** $137,067

Mr. Lunsford stated that there had not been any subdivision paving alternates listed or any improvements to already paved roads. There will also not be any Trust Fund Safety improvements. Mr. Lunsford stated that the program was subject to availability of funding, right of way, and environmental review.

Chairman Hammer requested a new list of unpaved road throughout the entire county. He stated that latest list he had was from 2001. Mr. Lunsford stated that staff was currently working on a new list that he would forward to Chairman Hammer or County Manager Rick French once completed.

Commissioner Yoder asked how many miles of unpaved roads were left in Alexander County. Mr. Lunsford stated that there was approximately 70 miles of unpaved roads in Alexander County, which he felt was on the high side when comparing to surrounding counties.

Chairman Hammer called the public hearing to order and requested any public comment.

Public Comment

Claude Reeves stated that he lived in the Ridge Creek Subdivision off of Jake Reece Court. He stated that the road had been staked since the first of the year but no work had been completed and he noted that he had called the NCDOT and no one could tell him

when the work would be completed. Mr. Reeves stated that the road was in bad condition and he was concerned that the road had not been included in the list for paving.

Clay Lunsford replied that Jake Reece Court was included in the 2004-2005 Secondary Road Program. He noted that he would speak with Mr. Reeves after the presentation regarding his road paving.

There being no further public comment, Commissioner Keever made a motion to close the public hearing. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

Commissioner Robertson made a motion to approve the 2005-2006 Secondary Road Improvement Program as presented. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

Chairman Hammer asked what road projects had been completed with the N.C. Moving Ahead funding. Mr. Lunsford replied that the following projects had been completed: Richey Road, Highway 64/90 from the golf course to the county line, Old Wilkesboro Road, and Martin Luther King Drive. He noted that all other projects, including signalization, had been delayed because of the state budget shortfall.

Chairman Hammer mentioned that the Board of Commissioners had met with Mr. Lunsford and NCDOT staff members on April 23, 2003 and developed a list of project priorities for the N.C. Moving Ahead funding. Included in that list was the widening of Highway 16 South to a 3-lane from Macedonia Church Road to Alspaugh Dam Road and the widening of Highway 90 to a 3-lane for its entirety. Chairman Hammer stated that the 2003 traffic count for Highway 90 was 9,000 and 13,000 for Highway 16 South. He also discussed the need for a traffic light at the intersection of Macedonia Church Road and Highway 16 South because of the prison. He felt these projects should be first priority when the funding was available for road construction.

Chairman Hammer also stated that there was a School Bus Stop Ahead sign on Alspaugh Dam Road that was no longer needed. Mr. Lunsford stated that the NCDOT Division Traffic Engineer would contact the School Bus Garage Director of Transportation to get that removed.

Mike Holder, Division 12 Engineer, explained that the NCDOT had cut back on all projects because of the budget shortfall and revenue shortfall. He also stated that the cost of concrete, steel, asphalt, and even fuel had increased the operating costs for NCDOT. He noted that the NCDOT would have been below the cash reserves in October and November 2005 and would not have been able to pay daily operating costs and payroll if spending for projects continued.

Commissioner Keever suggested cutting back on scraping and reseeding to save some fuel.

Commissioner Yoder stated that there were currently no roads in Alexander County that allowed trucks hauling 53 foot trailers to operate efficiently even though permits could be issued. He asked that a study be done to determine a road(s) in Alexander County for that purpose and he

mentioned Highway 16 from Taylorsville to Wilkesboro. Mr. Holder replied that 2 studies were currently underway for Highway 16 and 321.

The Board thanked Mr. Holder and Mr. Lunsford for the report. The Board also congratulated Mr. Lunsford on his forthcoming retirement in December and wished him the best of luck in the future.

PUBLIC HEARING: REZONING CASE 05-4: INGRAM FARM ROAD

Sylvia Turnmire, Director of Planning & Development, presented Rezoning Case 05-4 submitted by Gary & Shirley Brown, Michael & Gale Hoover, Phillip A. Hoover, Phillip G. Hoover, Lisa W. McNeely, Dwayne Warren, John Warren, Gary Warren, Matthew Warren, Michael Warren, Paul & Martha Warren, and Steve & Susan Wike. The applicants requested rezoning of properties located on both Warren Road and Ingram Farm Road from R-20 (Residential) to RA-20 (Residential-Agricultural). The size of the properties (18 total properties) is 106 acres and the existing land uses include manufactured homes, single-family site-built homes, agricultural, and vacant land. Ms. Turnmire stated that zoning within 100 feet of the properties was R-20 to the north, R-20 and RA-20 to the south, and RA-20 to the east and west. There are single-family site-built homes, agricultural property, and vacant land to the north, east, and west of the subject properties as well as single-family site-built homes and agricultural property to the south.

Ms. Turnmire stated that the applicants wished to rezone the property for future residential and farming uses. She also stated that Matthew Warren intended to place a singlewide manufactured home on his property.

Ms. Turnmire explained that the Alexander County Zoning Ordinances identified RA-20 as a zoning district intended to provide for low density residential and agricultural purposes, including single-family site-built homes and individual manufactured homes. Primary, common uses allowed in RA-20 include but are not limited to site-built, modular, and manufactured homes, as well as agricultural uses. Ms. Turnmire stated that all of the uses allowed in RA-20 should be considered, not only the use for which the applicants were applying.

Ms. Turnmire mentioned that the Alexander County Land Development Plan showed these properties as being in an "Urban Transition Area" due to the close proximity to the Town of Taylorsville's planning jurisdiction and she explained that the purpose of the Urban Transition class was "to provide for future intensive urban development on lands that are suitable and that will be provided with the necessary urban services to support intense urban development. Areas meeting the intent of Urban Transition classification are presently being developed for urban purposes or will be developed in the next 5 to 10 years to accommodate anticipated urban growth." Ms. Turnmire noted that the primary difference between the RA-20 and R-20 zoning districts is that RA-20 allowed for manufactured homes and R-20 did not. Most other residential and agricultural uses are allowed in both districts.

Ms. Turnmire stated that letters were sent by first class mail to the property owners within 100 feet of the parcel boundary and a sign was posted on the properties. She noted that staff received

3 calls in regards to the case including Sylvia Boutwell, adjoining property owner, who asked several questions but did not state a position to the request. An individual with plans to purchase property within the area also called with questions and no position. Greg Kiziah, adjoining property owner, called with several questions regarding permitted uses within the RA-20 and R-20 district. Ms. Turnmire informed the Board that Mr. Kiziah stated that he "was not interested in seeing any additional mobile homes placed on the property." He also expressed a desire to submit an opposition letter prior to the Planning & Zoning Commission Meeting; however, staff has not received such letter to date.

Ms. Turnmire informed the Board that the Planning & Development staff recommended approval of the rezoning request. She also stated that the Planning & Zoning Commission met on September 1, 2005 and unanimously recommended approval of the rezoning.

Chairman Hammer called the public hearing to order and requested any public comment. There being no public comment, Commissioner Robertson made a motion to close the public hearing. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

Commissioner Yoder made a motion to approve Rezoning Case 05-4. Commissioner Robertson seconded the motion. The Board voted unanimously in favor of the motion.

PUBLIC HEARING: REVOLVING LOAN FUND

David Icenhour, Economic Development Director, explained that the Revolving Loan Fund was created from state funds and was established for the sole purpose of supporting local economic development projects which created new employment opportunities. He stated that no local ad valorem taxes had been used to create the Revolving Loan Fund.

Mr. Icenhour requested approval of a $50,000 loan to Royale Comfort Seating Inc. from the Revolving Loan Fund to aid in the relocation of manufacturing equipment from Catawba County to Alexander County. He also stated that the public benefit derived from making this loan consisted of the creation of 50 new jobs and the retention of 150 jobs as well as an expanded tax base. Mr. Icenhour mentioned that the repayment terms of the loan would be annual payments over a 5-year period at one percent interest.

Chairman Hammer called the public hearing to order and requested any public comment. There being no public comment, Commissioner Keever made a motion to close the public hearing. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

Commissioner Keever made a motion to approve the $50,000 loan to Royale Comfort Seating from the Revolving Loan Fund to be paid back in annual payments over a 5-year period at one percent interest contingent upon loan documents being prepared and approved by the County Attorney. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

CHILD PROTECTIVE SERVICE REPORT

Karen Hoyle, Director of Social Services, informed the Board that there has been a significant increase in child neglect and abuse in Alexander County since 2003 and she noted that the trend was continuing. She presented graphs and charts explaining the number of reports and investigations for Child Protective Services for each month since 2000-2001. She also discussed in detail the number of reports and investigations for July and August 2005 including what type of abuse was involved, reporters of the abuse, and what location of the county the abuse took place.

Ms. Hoyle felt that a community wide effort was needed to halt and hopefully reverse the escalating trend of neglect and abuse. Therefore, she recommended a time-limited task force be formed to examine the current child neglect and abuse situation and to develop strategies aimed toward reversing this trend. She recommended representatives from the following organizations for the task force:

DSS Board Representative
School Superintendent
Sheriff
Police Chief
District Attorney
Chief District Court Judge
Health Director
Domestic Violence Shelter Director
Partnership for Children Director
Foothills Mental Health Director
Community Child Protection Team Representative
Social Services Director
Others deemed appropriate by commissioners

Commissioner Robertson suggested a county commissioner and a representative from the Clerk of Court's Office to serve on the task force as well.

Commissioner Robertson made a motion to approve the forming of a task force to develop strategies to stop child abuse and neglect. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

BUDGET ORDINANCE AMENDMENT #18

Rick French, County Manager, discussed the purpose of Budget Amendment #18, which included the following information:

Budget Amendment #18 – To budget for a refund to the N.C. Department of Juvenile Justice for 2004-2005 JCPC leftover balances. To increase the budget for site clean-up for economic development.

Commissioner Robertson made a motion to approve Budget Amendment #18. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

ALEXANDER COUNTY GOVERNMENT TRAVEL POLICY

Rick French, County Manager, presented a revised Travel Policy that was initially presented at the September 12, 2005 Commissioners' Meeting for review by the Board. Mr. French explained that this policy was similar to other counties and covered items such as reimbursement rates for meals and mileage, travel modes, travel advances, and items not reimbursable.

Commissioner Keever made a motion to approve the Alexander County Government Travel Policy as proposed. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

RESOLUTION FOR DISABLED AMERICAN VETERANS FORGET-ME-NOT WEEK

Commissioner Robertson presented the Disabled American Veterans Forget-Me-Not Week Resolution declaring the week of October 8 – 15, 2005 as the annual Forget-Me-Not campaign in the community to raise funds to be used for the benefit of disabled veterans and their families. Commissioner Robertson pointed out that the DAV offered free services to disabled veterans and their families such as filling claims for government benefits and help with medical and employment problems.

Commissioner Robertson made a motion to approve the DAV Forget-Me-Not Week Resolution. Commissioner Keever seconded the motion. The Board voted unanimously in favor of the motion.

OTHER BUSINESS

Rick French, County Manager, discussed the following issues during Other Business:

A. The Jail Committee will be meeting on Wednesday, October 5, 2005 at the Alexander County Courthouse. The purpose of the meeting will be to discuss the courthouse security, handicap concerns, and new facilities.

B. The DSS Open House is scheduled for Thursday, October 20, 2005 from 2:00 PM to 5:00 PM. The annual Clean Alexander Day is scheduled for October 22, 2005 from 8:00 AM to 4:00 PM. The Grand Opening of the Auditorium will be held on October 23, 2005 at 3:00 PM.

C. Commissioner Robertson, Health Director Leeanne Whisnant, and Mr. French will be attending the Foothills Mental Health Retreat in Boone on October 7-8, 2005.

D. A work session will be held on Monday, October 17, 2005 at the CVCC / Alexander Center.

E. County staff just received notice concerning upcoming NCDOT outreach forums that will focus on the subject of revenue and the large gap in transportation needs in the state. One of the forums will be held on Thursday, October 13, 2005 at the Broyhill Center on U.S. 321 in Lenoir from 6:00 PM to 9:00 PM.

F. Mr. French presented some revisions to the Alexander County Email, Internet, & Computer Resources Policy and the Substance Abuse Policy to be discussed at the next Commissioners' Meeting.

CONSENT AGENDA

A. Minutes from the September 12, 2005 Regular Commissioners' Meeting.

Commissioner Keever made a motion to approve the Consent Agenda. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

CLOSED SESSION – N.C.G.S. 143-318.11(a)(1, 4, 5, & 6) TO PREVENT DISCLOSURE OF CONFIDENTIAL INFORMATION, ECONOMIC DEVELOPMENT, CONTRACTUAL, & PERSONNEL

Commissioner Robertson made a motion to enter into Closed Session at 7:38 PM to prevent the disclosure of confidential information and to discuss economic development, contractual matters, and personnel issues pursuant to N.C.G.S. 143-318.11(a)(1, 4, 5, & 6). Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

ADJOURNMENT

There being no further business, Commissioner Keever made a motion to adjourn at 9:37 PM. Commissioner Yoder seconded the motion. The Board voted unanimously in favor of the motion.

William L. Hammer, Chairman

Jamie M. Starnes, Clerk to the Board

Nomination of 1-Bromopropane (1-BP) and 2-Bromopropane (2-BP) for Testing by the National Toxicology Program

submitted by:

Directorate of Health Standards Programs
U.S. Occupational Safety and Health Administration
December 1999

I. Basic Chemical Information:

	1-Bromopropane	2-Bromopropane
Synonym	*n*-propyl bromide	isopropyl bromide
CAS Registry Number	106-94-5	75-26-3
Description	flammable liquid	flammable liquid
Freezing Point	-110 °C	N/A
Boiling Point	69 °C	59 °C
Vapor Pressure	143 mm Hg	N/A
Vapor Density (air=1)	4.3	N/A
Specific Gravity	1.35	1.31
Flash Point (closed cup)	21 °C	22 °C
Decomposition Products	hydrogen bromide	hydrogen bromide
Solubility	0.25 g/100 mL water (20°C)	N/A

References:

Hazardous Substances Databank, National Library of Medicine
Elf Atochem. Safety Data Sheet for n-Propyl Bromide. 1997

II. Production, Use, and Exposure Information:

A. Production and Use:

Until recently, 1-BP was not produced in the U.S. in significant quantities (the major producers were located in the U.K. and Asia). Hence, 1-BP does not appear on EPA's TRI database and is not listed as a Hazardous Air Pollutant under the Clean Air Act. However, several companies have begun domestic production, anticipating major inroads into markets currently

dominated by other halogenated solvents. Two important factors have opened the door for potentially enormous increases in the domestic market for 1-BP over the next several years, perhaps even within several months: (1) although 1-BP has a small but non-zero capacity to degrade stratospheric ozone, it can substitute for potent ozone-depleters (e.g., hydrochlorofluorocarbons) in several major uses -- as EPA continues to place severe restrictions on CFCs and HCFCs, companies will look to unregulated substances such as 1-BP to replace them; and (2) in April 2000, OSHA's 1997 workplace exposure standard for methylene chloride (MC) will take full effect -- OSHA has already received numerous reports of companies switching to 1-BP rather than installing ventilation or other controls needed to reduce employee MC exposures to the requisite 25 ppm level.

Various estimates have been made of the potential market for 1-BP in the key uses to which it is likely to be put: metal cleaning and degreasing, adhesives (especially for assembling polyurethane and other foam products), and aerosol spraying. Note that all of these uses are in practice highly emissive applications, resulting in substantial releases to the ambient environment and substantial exposure to workers (unless engineering control measures are installed, which is not likely given that the major reason for switching from existing materials to 1-BP is to avoid such expenditures):

- Currently, approximately 240 million pounds of chlorinated solvents (principally trichloroethylene, perchloroethylene, and MC) are used in the U.S. each year for vapor degreasing and cold metal cleaning (1). Assuming that 1-BP remains unregulated, the combined effects of the OSHA MC rule (and anticipated OSHA perchloroethylene standard) and continued EPA regulation of the three chlorinated solvents under the NESHAP program place an upper bound on 1-BP use in these areas of 240 million pounds (IRTA notes that the actual substitution could even exceed this amount, since consumptive use of the three "traditional" solvents is currently reduced due to requirements for controlling evaporative emissions, which might not obtain for 1-BP). Similarly, virtually all of the adhesive used in foam fabrication has shifted from trichloroethane (TCA) to MC-based during the past decade following the TCA production ban; all of that market (68 million pounds annually) could potentially be replaced by 1-BP. A similarly large quantity (over 130 million pounds annually) of HCFCs are used in aerosol applications, and 1-BP could take over some or all of this market as well.
- One manufacturer (2) has estimated that an additional 2.5 million pounds of 1-BP might be used annually within the next three years as a cleaning agent in the repair and maintenance of plant machinery alone.

- According to a European research group, at a June 1999 meeting of the Montreal Protocol Open-Ended Working Group, a technical committee reported that solvent uses of 1-BP would expand to 132 million pounds within five years, consuming five percent of world bromine production (3). It is of course difficult to compare this worldwide figure with the domestic estimates above. If, however, these various estimates are even partially borne out, 1-BP could become one of the relatively few chemical substances used in the 10^7 - 10^8 million pound range with little or no adequate data available to shed light on "reasonably anticipated" reproductive toxicity and genotoxicity/carcinogenicity.

Note that 2-BP is not produced deliberately for commercial purposes in the U.S., but is at present an inevitable contaminant of 1-BP synthesis. OSHA has analyzed several samples of commercial 1-BP in the past year and found 2-BP present in each of them, in concentrations ranging from 0.1 to 0.2 percent. Therefore, if roughly 300 million pounds of 1-BP are produced in a future year, nearly 1 million pounds of 2-BP, which appears (see below) to be the more toxic isomer, will be produced concomitantly.

Note also that estimates of production assume maintenance of the status quo under EPA's Significant New Alternatives Policy (SNAP) for phasing out ozone-depleting chemicals. As a result of EPA's not yet disapproving 1-BP for any application following a petition from the Brominated Solvents Committee, it can be used for any purpose at present. EPA published an Advance Notice of Proposed Rulemaking for 1-BP in early 1999 (6a) that did not signal whether it would be approved or disapproved; EPA plans to publish a proposed rule in early 2000 which may limit 1-BP use to certain applications where substitution is likely to be of net benefit to the ozone layer (e.g., perhaps proposing not to allow substituting 1-BP for MC, as the latter chemical has a lower ozone-depleting potential).

B. Employee Exposure:

OSHA has no information at the present time on the possible number of U.S. residents who might be exposed to ambient emissions of 1-BP under various scenarios of production and use. However, even if only worker exposure is considered, and just exposures resulting from substitution away from MC are used as a lower bound, the potential breadth of 1-BP exposure elevates it beyond the exposure potential of many other substances tested by NTP in recent years. According to OSHA estimates in 1997, more than 100,000 workers are exposed to MC (4) in metal cleaning and adhesive applications alone (note: unlike comparable numbers from NIOSH's National Occupational Exposure Survey often used in NTP documents, this figure represents only

workers believed to be exposed to the substance as part of their regular duties, not total employment in establishments where the substance is used in the given application).

Limited industrial hygiene data suggest that 1-BP exposure will be quite substantial in magnitude as well as in breadth (number of workers exposed). OSHA has analyzed approximately 30 personal samples (2- to 4-hour time-weighted averages) for 1-BP (and a comparable number for 2-BP) at three facilities during the past year (5). Most 1-BP TWAs were approximately 40-80 ppm, with exposures ranging as low as 0.05 ppm and as high as 135 ppm. 2-BP exposures were generally quite consistent with the 0.1-0.2 percent contaminant levels in the primary product; TWA concentrations ranged from below the limit of detection to 0.28 ppm (0.3% of the 82 ppm exposure to 1-BP measured simultaneously for this worker).

In November 1998, NIOSH performed a detailed evaluation of 1-BP exposures at a jet aircraft seat cushion manufacturing facility in North Carolina where adhesives containing 1-BP were used (6). Sixty-nine full-shift personal samples were collected, and the average 1-BP TWA was 170 ppm, with individual worker exposures ranging between 60 and 380 ppm. Eleven area samples were also taken, with 1-BP concentrations all clustered between 107 and 161 ppm.

Therefore, depending on whether one interprets the existing animal data to support a NOAEL of 400 ppm or 200 ppm (see Section V below), it is clear that absent regulation, many workers will be exposed to concentrations of 1-BP within a factor of five of, and in some cases exceeding, the NOAEL in rodents. If the traditional 100-fold "safety factor" was applied to the NOAEL (whether to derive a dose thought likely to be below a threshold for human toxicity or a dose 100-fold lower than a "point of departure" that may represent an LED_{10} for the test animals), then most current 1-BP exposures would exceed this level by at least tenfold and by as much as 200-fold. OSHA believes a very high priority should be placed on conducting tests that would shed light on whether such large exposures pose a potential for human reproductive toxicity and in addition may pose a cancer risk, before the number of persons exposed grows from the hundreds to the tens of thousands or more.

References:

1. Comments of Institute for Research and Technical Assistance (Santa Monica, CA) to EPA "SNAP" Docket (A-91-42), 29 April 1999.

2. Comments of CRC Industries Inc. (Warminster, PA) to EPA Docket A-91-42, 23 March 1999.

3. http://www.protonique.com

4. OSHA Methylene Chloride Final Rule (62 FR 1493-1619), 10 January 1997.

5. Personal communication from OSHA Salt Lake Technical Center to Adam Finkel, October 1999.

6. Comments of NIOSH (Christopher Reh, Ph.D.) to Docket A-91-42, 1 July 1999.

6a. EPA ANPRM on n-propyl bromide, 64FR 8043-8047, 18 February 1999.

III. Toxicology:

A. Human Data

OSHA is not aware of any epidemiological studies or published case reports of toxicity except for general statements that 1-bromopropane (1-BP) is able to cause central nervous system depression, presumably at high concentrations (7). However, occupational exposure to the closely related structural analog, 2-bromopropane (2-BP), likely caused reproductive and hematologic effects reported in Korean and Chinese workers (see section IV. B below).

B. Experimental Animal Information

Single Dose Toxicity - 1-BP is not particularly toxic based on acute lethality. The four-hour LC50 in the rat is 7000 ppm (8) and the oral LD50 for the rat is greater than 2 g/kg (8). The LD50s for rat and mouse are 2.9 g/kg and 2.5 g/kg, respectively, by intraperitoneal injection (7).

Repeated Dose Toxicity - Results were reported from several repeated dose studies by inhalation in rats. ClinTrials BioResearch Laboratories of Quebec, Canada reported on a 28-day exposure study (9) and 13-week exposure study (10) with 1-BP. These were sponsored by Albemarle Corporation and submitted to EPA as part of the requirements for consideration under the SNAP program. A series of 1-BP exposures ranging from 7 days to 12 weeks have been conducted by university laboratories in Japan. The toxicity of 1-BP and 2-BP were compared for certain endpoints. The results were published in abstract form as part of 1997, 1998, and 1999 Japanese Industrial Hygiene and Occupational Health meetings.

ClinTrials Studies - In the 28 day study, groups of 10 male and 10 female Crl:CD® (SD)BR Sprague-Dawley rats were exposed to 0, 2, 5, and 8 mg/L (0, 400, 1000, or 1600 ppm) for 6 hours/day, 5 days/week. The

high dose produced significant mortality in males and females by the end of the study period. Clinical signs of neurotoxicity (convulsions, incoordination, hunched posture, etc.) were evident at the mid- and high dose. This was confirmed by impairment in a modified functional observation battery (FOB). Several organ weights (liver, kidney, brain, lung) were marginally increased; hematologic parameters (red blood cells, hemoglobin, etc.) were marginally decreased; and widespread histopathological damage was found in several tissues (testis, bone marrow, brain, spinal cord, kidney, bladder, etc.) at the 8 mg/L (1600 ppm) exposure. Where examined, many of these changes were still present to a lesser extent at the 5 mg/L (1000 ppm) exposure. While there were no apparent clinical and hematological effects at the 2 mg/L (400 ppm) exposure, mild vacuolization in the white matter of the brain was evident in almost half the animals (5/10 males; 4/10 females) examined indicating some neurological damage at this exposure level.

In the 13-week study, groups of 15 males and 15 female rats (same strain) were exposed to 0, 0.5, 1, 2, 3 mg/L (0, 100, 200, 400, and 600 ppm) for 6 hours/day, 5 days/week. The investigators found no significant treatment-related clinical, functional or hematological effects. There was a significant increase in the relative liver weights in the male rats at the two highest doses (11). This was accompanied by mild centrilobular hepatocyte vacuolation in 6/15 male rats (statistically significant elevation) at 3 mg/L (600 ppm) and 3/15 rats (non-significant elevation) at 2 mg/L (400 ppm). The combination of liver weight increases with histopathological changes indicates slight to mild liver toxicity at the 2 mg/L (400 ppm) and 3 mg/L (600 ppm) exposures. No vacuolization of brain tissue was reported at any exposure levels in this study. Based on these findings the authors reported a No Observed Adverse Effect Level (NOAEL) of 1 mg/L (200 ppm).

Japanese Studies - Investigators at Nagoya University School of Medicine exposed groups (9 to 11 rats/group) of male Wistar rats to 200 ppm, 400 ppm, 800 ppm, and 1000 ppm for 8 hours/day, 7 days/week for up to12 weeks (12, 13, 14). They primarily evaluated effects on neurological function and reproductive organs. Body weight gain and several organ weights (liver, brain, prostate, seminal vesicle, etc.) were significantly decreased at 1000 ppm (12). There was a time- and concentration-dependant decrease in grip strength and rat tail motor nerve conduction velocity (MCV) and prolonged motor nerve distal latency (12, 13). At 1000 ppm, statistically significant neurophysiological effects were evident by four weeks of exposure (12). There was evidence of myelin degeneration in the tibial nerve and neuroaxonal swelling in the medulla oblongata at the 1000 ppm and 800 ppm exposure levels (12, 13). The absolute weight of most reproductive organs and blood testosterone were significantly lower than controls at the 800 ppm level (14). The seminal

vesicle was particularly effected by 1-BP exposure with about a 50 percent reduction in weight in 800 ppm-exposed animals (14). This organ weight was still significantly reduced in the lowest exposure group (200 ppm). 1-BP also caused decreases in epididymal sperm density and motility but did not effect spermatogonia development in the testis characteristic of 2-BP exposure (13).

The Nagoya University group also investigated the effect of a seven day exposure to 1-BP on the reproductive organs in male Wistar rats (15). Animals (nine per group) were exposed to 200 ppm, 400 ppm, and 800 ppm. There was a significant decrease in body, prostate and seminal vesicle weights at 800 ppm. This exposure level also significantly reduced the epididymal motile sperm rate and the percentage of abnormal sperm without affecting sperm count. The reduction in motile sperm rate showed a concentration dependency and was significantly less than control, even at the 200 ppm level. Minor histopathological changes in the tibial nerve were found at the 800 ppm level.

Another Japanese group studied testicular toxicity in male Wistar rats exposed to 1500 ppm, 6 hours/day, 5 days/week for 3 weeks followed by a 2 week recovery period (16). Exposure to 1-BP caused a time-dependent decrease in the number of spermatogonia followed by incomplete recovery during the post-exposure period.

C. *In vitro* and Other Short-term Tests - 1-BP was reported to be mutagenic with and without metabolic activation in the Ames assay using Salmonella strains TA1535 and TA100 (17). The compound apparently has also tested negative in the reverse mutation assay using the Ames method (18). It was negative in the micronucleus test (19) and negative for dominant lethal activity in males rats given 400 mg/kg (20). Like other alkyl bromides, 1-BP is an alkylating agent and has potential to react with nucleophilic sites in cellular macromolecules.

References:

(7) Patty's Industrial Hygiene and Toxicology. Clayton G.D. and Clayton F.E. (eds). John Wiley Sons, New York, 1981-1982 pp. 3259

(8) ICF Memorandum. Acceptable Industrial Exposure Limit for N-Propyl Bromide. September, 1998

(9) ClinTrials. A 28 Day Inhalation Study of a Vapor Formulation of ALBTA1 in the Albino Rat. Report No. 91189. May, 1997

(10) ClinTrials. A 13 week Inhalation Study of a Vapor Formulation of ALBTA1 in the Albino Rat. Report No. 91190. February, 1997

(11) ICF Memorandum. Acceptable Industrial Exposure Limit for n-Propyl

Bromide. September, 1998

(12) Ichihara, Shah, Shibata, Takeuchi, and Tomoeda.. Neurotoxicity of 1-Bromopropane and 2-Bromopropane. Tokai Region Conference, 1997

(13) Ichihara, G. Reproductive and Other Disorders Due to Bromopropanes; Presented at 1999 Meeting of Japan Society for Occupational Health. *Journal of Occupational Health* **41:** 137, 1999

(14) Ichihara, G. et al. Histopathological Changes of Nervous System and Reproductive Organ and Blood Biochemical Findings in Rats Exposed to 1-Bromopropane; Presented at 1999 Meeting of Japan Society for Occupational Health. *Journal of Occupational Health* **41:** 513, 1999

(15) Wang, H. et al. Subacute Effects of 1-Bromopropane on Reproductive Organs and the Nervous System; Presented at 1999 Meeting of Japan Society for Occupational Health. *Journal of Occupational Health* **41:** 306, 1999

(16) Kasai, T. et al. Histopathological Study of Testicular Toxicity in Rats Exposed to 1-Bromopropane; Presented at 1999 Meeting of Japan Society for Occupational Health. *Journal of Occupational Health* **41:** 308, 1999

(17) Barber, E. et al. A Procedure for the Quantitative Measurement of the Mutagenicity of Volatile Liquids in the Ames Salmonella/microsome Assay. *Mutation Research* **90:** 31-48, 1981

(18) Elf Atochem. Ames Assay - Reverse Mutation Assay on Salmonella Typhirium. N-Propyl Bromide. HIS1005/1005A. 1994

(19) Elf Atochem. Micronucleus Test by Intraperitoneal Route in Mice. N-Propyl Bromide. Study No. 12122. September, 1995

(20) Saito-Suziki et al. Dominant Lethal Studies in Rats with 1,2-Dibromo-3-chloropropane and Its Structurally Related Compounds. *Mutation Research* **101:** 321-327, 1982

IV: Disposition and Structure-Activity Relationships:

A. Absorption, Distribution, Metabolism and Excretion:

OSHA is not aware of any available studies that characterize the toxicokinetics of 1-BP in experimental animals. Metabolism experiments *in vitro* with rat liver subcellular fractions indicate that 1-BP is conjugated with glutathione (21). It has also been shown to deplete glutathione in rat hepatocytes *in vitro* (22). There is some indirect qualitative evidence that oxidation to a reactive epoxide by the mixed function oxidase (MFO) system may occur *in vitro* (21), but its existence *in vivo* has yet to be established.

B. Structure-activity Correlations and Considerations:

There is both human and animal evidence that the close structural isomer of 1-BP, 2-BP, interferes with ovulation in females and sperm production in males. 2-BP causes hematopoietic toxicity as well. In a study of Korean workers (25 females and 8 males) exposed to a cleaning solvent containing >95 percent 2-BP for up to two years, it was reported that amenorrhea accompanied by high follicle stimulating hormone (FSH) levels occurred in 64 percent (16 ex. 25) of the exposed females; azoospermia (absence of sperm), oligospermia (deficiency of sperm), or reduced sperm motility occurred in 75 percent (6 ex. 8) of the exposed males; pancytopenia (reductions in erythrocytes, leukocytes, and platelets) occurred in 21 percent (7 ex. 33) of the workers (23). Reportedly, typical 2-BP concentrations in this setting averaged about 20 ppm, but this information may not be reliable.

An investigation of a Chinese chemical plant that produced 2-BP found sperm abnormalities and anemia among exposed workers (24). The Nagoya University group has shown similar reproductive effects in male (25) and female rats (26) exposed to 2-BP. Male rats exposed to 300 ppm and above had significant reductions in testis weight, sperm count, and sperm motility. Erythrocytes, leukocytes, and platelet counts in the peripheral blood were also significantly reduced at the same exposures. There were significant irregularities in the estrous cycle and decreased numbers of ovarian follicles in female rats exposed to 300 ppm and above. Another halogenated propane, 1,2-dibromo-3-chloropropane, is a well-recognized testicular toxicant.

The close structural analog, bromoethane (BE), underwent toxicity testing by the National Toxicology Program (27). In these studies, two-year inhalation exposures to female $B6C3F_1$ mice resulted in a significant increase in benign and malignant neoplasms of the uterus at the highest exposure (400 ppm). On this basis, the test report concluded that there was clear evidence of carcinogenic activity for the female mouse. There was some/equivocal evidence of carcinogenicity for other species/sex/site combinations. BE was also mutagenic in Salmonella strain TA100 and induced sister chromatid exchanges in Chinese hamster ovary cells.

References:

(21) Jones, A. and Walsh, D. The Oxidative Metabolism of 1-Bromopropane in the Rat. *Xenobiotica* **9**: 763-772, 1979

(22) Khan, S. and O'Brien, P. 1-Bromoalkanes as New Potent Nontoxic Glutathione Depleters in Isolated Rat Hepatocytes. *Biochem. Biophys. Res. Commun.* 179: 436-441, 1991

(23) Kim, Y. et al. Hemopoietic and Reproductive Hazards of Korean Electronic Workers Exposed to Solvents Containing 2-Bromopropane.

Scand J Work Environ Health **22:** 387-391, 1996

(24) Takeuchi, Y. et al. A Review of 2-Bromopropane: Mainly on its Reproductive Toxicity. *J Occup Health* **39:** 179-191, 1997

(25) Ichihara, G. et al. Testicular and Hemopoietic Toxicity of 2-Bromopropane, a Substitute for Ozone Layer-Depleting Chorofluorocarbons. *J Occup Health* **39:** 57-63, 1997

(26) Kamijima, M. et al. Ovarian Toxicity of 2-Bromopropane in the Non-Pregnant Female Rat. *J Occup Health* **39:** 144-149, 1997

(27) National Toxicology Program. Toxicology and Carcinogenesis Studies of Bromoethane in F344/N Rats and B6C3F_1 Mice. *Technical Report-363*. October, 1989

V. Summary:

Two consulting firms, ICF Inc. and Environ (the latter group continuing to provide comments to EPA under the name Life Sciences Consultancy), have evaluated the toxicological data and reached slightly different conclusions. ICF concluded the NOAEL was 400 ppm based on its interpretation of the reproductive endpoints. Environ concluded that the NOAEL was 200 ppm based on the studies of Ichihara et al. (12-14) showing decreased sperm counts at 400 ppm and greater. 400 ppm is also a LOAEL for white matter vacuolization in the brain of rats. More recent work by Ichihara et al. and by Wang et al. (15) suggest that effects on the male reproductive system are visible even at 200 ppm.

OSHA suggests that there is a pressing need to pin down the "true" NOAEL—even better, to use standard study designs and statistical methods to establish a "benchmark dose" for each compound, so that regulatory agencies can rationally consider setting risk-based exposure limits. Moreover, until two-year cancer bioassays are conducted on each compound, agencies have no way to assess whether reproductive toxicity is indeed the most sensitive adverse endpoint.

VI. Ongoing Toxicological and Environmental Studies in the Government, Industry, and Academia:

OSHA is aware of two ongoing efforts to expand the toxicological data base for 1-BP. In a May, 1999 letter expressing support for the approval of 1-BP as a substitute for ozone-depleting substances in EPA's SNAP program, the Brominated Solvents Committee (BSOC), a consortium of three 1-BP

producers, acknowledged sponsoring a two generation reproductive effects study and a developmental study in rats by inhalation (28). The study design will presumably exceed current EPA and OECD guidelines and include evaluation of sperm morphology and estrous cycle. The current status, study protocol, and timetable for completion of these studies was not stated in the submission. OSHA learned recently that these studies were halted in mid-1999 because of infertility in the control groups. BSOC has restarted the studies very recently (although reportedly using the same contractor and supplier of lab animals) and expects to provide results to EPA by July 2000. Given the preliminary data presented at the recent Annual Meeting of the Japan Society for Occupational Health, research to further understand the reproductive and neurological effects of 1-BP in experimental animals will likely be pursued by investigators at Nagoya University and elsewhere in Japan.

Reference:

(28) Brominated Solvents Committee. Letter to EPA Air Docket #A-91-42 Regarding Support for SNAP Approval of n-Propyl Bromide. May, 1999

VII. Rationale for Recommendation and Suggested Studies:

Beyond the potential for widespread occupational and possible environmental exposure, the information provided by preliminary toxicological studies on 1-BP and data from related alkyl bromides raise various concerns with regard to human health. The effects on reproductive tissue of male rats caused by short exposures to 1-BP suggest the need for longer term studies to assess reproductive function. The reproductive impairments in female and male workers exposed to its isomer, 2-BP, reinforce the need to evaluate this endpoint in both sexes along with effects on human development. The mixed results in the limited genotoxicity testing of 1-BP, its alkylating potential, and the tumorigenicity of the structurally-related BE suggest the need for additional short-term tests and a cancer bioassay. The clear neurotoxicity at high doses combined with abnormal neurophysiology at lower exposures indicate the need for more complete evaluation of neurological function. Additional toxicity testing would provide the necessary data to better identify hazard and estimate risk to workers which are essential to deriving exposure limits that protect worker health. Suggested studies are as follows. Input from the various National Toxicology Program (NTP) committees is encouraged.

OSHA believes it is essential that both reagent-grade 1-BP and 2-BP be tested separately, if at all possible. Because commercial 1-BP contains significant trace levels of 2-BP, a “negative” result from testing 1-BP alone may

not shed light on the hazard potential of the commercial product. On the other hand, a positive result if the commercial product were tested might not indicate that pure 1-BP (assuming it could be formulated in quantity) is necessarily hazardous.

OSHA recommends that NTP consider the following tests:

- Carcinogenicity Study - The full two year National Toxicology Program (NTP) bioassay protocol in both sexes of rats and mice is recommended for both compounds. The test compounds should be administered by inhalation at the maximum tolerated exposure and at least two other non-zero exposures. Specialized studies evaluating DNA binding, oncogene activation, cell proliferation, etc. should be considered as appropriate.

- Multi-generation Reproductive Study - Unless there is a successful and thorough completed study from industry sponsors, a reproductive study in exposed rats of both sexes covering at least two generations of mating is recommended. Exposure should be by inhalation and conducted by accepted NTP protocols. It is strongly recommended that spermatogenesis, estrous cycle, and hormonal endpoints be measured as well as the standard fertility and pregnancy outcomes.

- Developmental Studies - It is recommended that developmental effects be evaluated in two species. Test compounds should be administered to pregnant animals by inhalation from the period of implantation to the end of gestation. The studies should be conducted by standard protocols and the usual maternal and fetal endpoints examined.

- Subchronic Neurotoxicity Study - It is recommended that neurological endpoints be evaluated during the standard 14 week exposure study in rats. These should include a Functional Observation Battery, neurophysiological endpoints, and specialized neuropathology as appropriate.

- Genotoxicity - A battery that adequately evaluates mutagenicity and clastogenicity in mammalian systems using sensitive *in vitro* and *in vivo* test methods is recommended.

- Toxicokinetic/Mechanistic Studies - It is recommended that toxicokinetics of the test compounds be evaluated following inhalation exposure over the appropriate dose range. The extent of absorption, tissue distribution, body residence time, major metabolites and pathways of elimination should be identified. Additional studies that provide a better understanding of target organ dosimetry, mode of action or dose - response is also suggested.

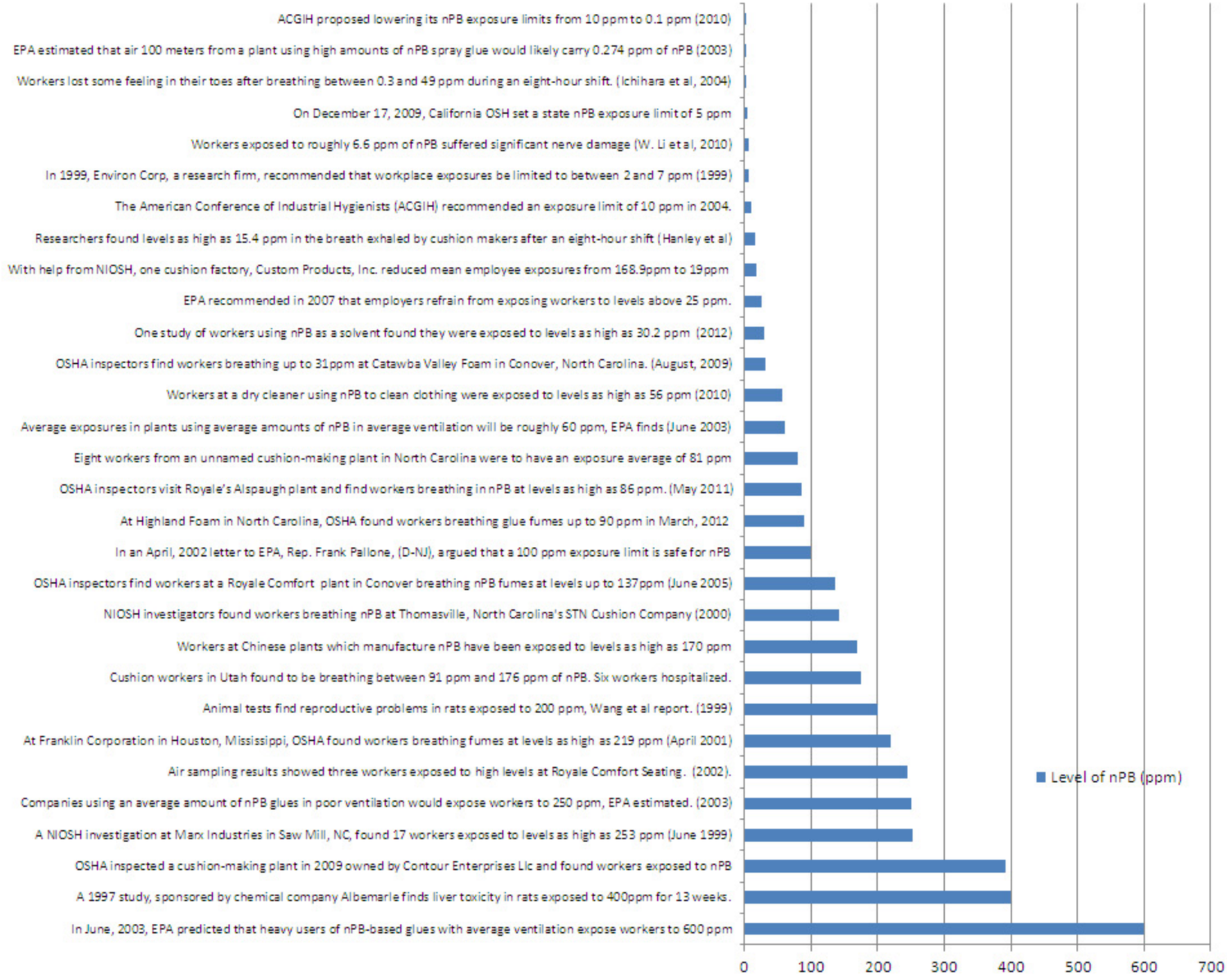
Date: 11-16-2006
Subject: Conversation, which included Dr. Hillel Magid, to review nPB usage distribution between adhesive, aerosol and solvent applications
Participants: M. Sheppard (EPA), K. Schlueter (EPA), J. Cromwell (Stratus Consulting), Dr. H. Magid (Environmental Consultant)

1. How much nPB is used in Aerosol Cleaning?
    - Boeing, Clean Tech Article, using nPB to clean air wings (wipes)
    - China produces large quantities of cheap, good cleaner and the only concern by users is compatibility with products it is cleaning
    - Large companies proactive about nPB use but should be, they are afraid to use nPB because of large lawsuits from users (workers)
        - CA—Health Department to regulate nPB
        - European Union—labeling nPB as highly flammable

    Liability concern
    - Smaller companies are less concerned because wages are low and likely employ illegal immigrants
    - Big companies are more concerned with liability because they are more susceptible
    - OSHA is tough but their budget is small and are not going to crack down on small businesses
    - Large companies in the long run avoid rework and have improved processes which eliminates the need for portable cleaners

2. How many fume hoods being used per firm?
    - Small companies have a need for rework operations
    - Engineer in house hose/motor apparatus to pull fumes out of rework area (fume hood device)
    - Or rework all components at one time—end of shift all items for rework at one time
    - Price for fume hood: $1000-1500
    - Use of nPB much cheaper than using flammables
    - Firms will write off ventilation costs
    - Ventilation costs will not be a deterrent to using nPB

nPB Exposures and Recommended Limits



Elf-Atochem statement

Home Page Up romocarbon 2 Greenpeace

The following is a statement published by Elf-Atochem (this has been reproduced verbatim and any errors are their's). Please note that the formatting of bulleted phrases has been slightly modified to suit our html theme:

Product Health & Safety Department

5th December 1997

n-Propyl Bromide (nPB) and solvent use

Elf Atochem's position relating to potential health risks

Because of a recent information from the Environmental Protection Agency in the US, we feel it has become necessary to clarify Elf Atochem's position regarding potential effects of nPB to health and reiterate our reservations on its use as a substitute for main halogenated solvents.

Our fears revolve around the serious risks and worries of solvent use: genotoxicity, carcinogenicity, and toxicity on reproduction.

This is for the following reasons:

- nPB is a chemical reaction agent for alkylation, and this reaction is potentially present at a biological level where it can cause the following serious effects:
  - genotoxicity/carcinogenic (by altering DNA)
  - effects on reproduction (by attacking the cells of male and female reproduction organs; teratogenic effects/foetus)
  - haematological problems (by attacking bone marrow cells)
- nPB is part of a high risk group: several made up of a bromoaliphatic structure show the above mentioned toxicological properties (for example, ethyl bromide, isopropyl bromide, dibromoethane, bromohloroethane, dibromochloropropane);
- The available toxicological information on nPB shows a doubt concerning its genotoxicity
- Used as a solvent, there is a total lack of toxicological data relating to carcinogenicity and reproduction (see attachment)

However, one must remember that when Elf Atochem, CFC producer, wanted to substitute CFCs with the new HFC/HCFCs, complete toxicological programmes had already been launched (PAFT), in collaboration with other producers, to show the harmlessness of each of these substitutes, especially in the fields of genotoxicity, carcinogenicity and reproduction. Today, we think that a similar route should be followed to evaluate the health risks if we wish to develop a new main halogenated solvent instead of the old chlorinated and fluorinated solvents.

Furthermore, it is advisable to remember recent incidents occurred to man due to early and uncontrolled use of isopropyl bromide in a solvent application. In 1995 we learnt that in Korea isopropyl bromide had caused some 20 serious cases involving problems with reproduction (stopping spermatogenesis, stopping ovarian cycle) and anaemia following use as a degreasing solvent. This information is now published in toxicology literature (KIM H.Y., JUNG K *et al* "Hematopoietic and Reproductive Hazards of Korean Workers Exposed to Solvents Containing 2 bromopropane" Scand. J. Work Environ, Health 1996, 22, 387 - 391). A year later, 25 similar cases, discovered in China confirmed the reprotoxic and hematotoxic impact of BiPon humans (ICHIHARAM. *et al* "Study from

a View Point of Labour Hygiene of 2-bromopropane Producing Plant in China" presented by Nagoya University to Japanese Industrial Hygiene Society, April 9 - 11, 1997). At the same time, tests on rats showed the same type of toxic effects from concentration of 300 ppm by inhalation (ICHIHARA G. *et al.* "Testicular Toxicity of 2-bromopropane". J. Occup. Health, 1996, 38, 205 - 206.)

In the context of following "Responsible Care" to which Elf Atochem subscribes, this data on isopropyl bromide has driven Elf Atochem to the voluntary class of reprotoxic for isopropyl bromide in its Health and Safety Data Sheet which has led to the T labelling ("toxic", skull) and R 60 ("can affect fertility"). At the same time, we have informed the French authorities according to the Control of Chemical Products Law (1977) and in June 1997 we sent them a request for classification as "toxic for reproduction in category 1 (effect proved in humans)" and submission to the EU. France wished to add a phrase R 48/20, to give the anaemic affects observed in humans..

In conclusion, given current knowledge, our worries on the toxicology of nPB remain intact. As long as the necessary toxicological studies are not carried out, it will not seem reasonable to recommend nPB in solvent use for which exposure is not easily controlled.

ATTACHMENT

n-PROPYL BROMIDE

TOXICOLOGICAL DATA NEEDED

◆ ACUTE TOXICITY	
oral route	available
dermal route	available
inhalation route	available
◆ LOCAL EFFECTS	
cutaneous irritation	available
ocular irritation	available
sensitisation	available
◆ GENOTOXICITY	
Ames test	available
micronucleus test	available
gene mutation in cultured cells (L 5178 Y mouse lymphoma cells)	available
DNA alkylation assay (DNA adducts)	to be performed*
in vivo unscheduled DNA synthesis	to be performed
◆ TOXICITY FOR REPRODUCTION	
teratogenicity study in rats	to be performed
teratogenicity study in rabbits	to be performed
fertility study in rats	to be performed
◆ REPEATED DOSE TOXICITY	

REPEATED DOSE TOXICITY	
subacute toxicity	done
subchronic toxicity	done
chronic toxicity	to be performed
CARCINOGENICITY STUDY	to be performed

*The colour of the text in red has been added by Protonique to highlight the tests that have not yet been performed.

E&OE

We, at Protonique SA, are grateful to the authors for the kind permission to reproduce this Elf Atochem data.

To return to where you left off, on the page on bromocarbon solvents, click here

This page last revised 13.09.98 Go to Text-only Home Page

FRANKLIN CORPORATION v. PAULINE TEDFORD, LORA SMITH, JUDY HAIRE AND SAMANTHA MIXON

NO. 2007-CA-01454-SCT

SUPREME COURT OF MISSISSIPPI

18 So. 3d 215; 2009 Miss. LEXIS 426

September 10, 2009, Decided
May 14, 2009, Filed

PRIOR HISTORY: [1]**
COURT FROM WHICH APPEALED: CALHOUN COUNTY CIRCUIT COURT. DATE OF JUDGMENT: 07/26/2007. TRIAL JUDGE: HON. ANDREW K. HOWORTH.
Franklin Corp. v. Tedford, 2009 Miss. LEXIS 169 (Miss., Apr. 16, 2009)

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellee employees sued appellant employer alleging multiple claims for batter and intentional infliction of emotional distress that arose from injuries sustained in the course of their employment. A jury returned a verdict in favor of the employees. The Calhoun County Circuit Court (Miss.) denied the employer's motions for judgment notwithstanding the verdict (JNOV), or in the alternative for a new trial or remittitur. The employer appealed.

OVERVIEW: The employer was a furniture manufacturer. The employer used a certain adhesive that contained a neurotoxin and it was necessary to have the area well ventilated. Despite the savings the employer enjoyed from using the adhesive it did not install mechanical ventilation exhausts outside the building on the glue line. The employees eventually were hospitalized because of their exposure to the neurotoxin. At issue on appeal was the application of the intentional tort exception to the Mississippi Workers' Compensation Act. Miss. Code Ann. § 71-3-1 et seq. The Supreme Court found that given the considerable amount of testimony offered by the employees and the management personnel of the employer the denial of the JNOV motion was proper. The experts' testimony was properly admitted under Miss. R. Evid. 702 because their qualifications were not legitimately questioned, and their testimony was sufficiently relevant and reliable. There was sufficient evidence to meet the "clear and convincing" standard required for punitive damages under Miss. Code Ann. § 11-1-65 and the court's determination of the employer's net worth at the time of judgment was proper.

OUTCOME: The judgment was affirmed.

CORE TERMS: exposure, ventilation, glue, punitive damages, glue-line, net worth, ppm, intent to injure, exclusivity, intentional torts, knowingly, willful, air, expert testimony, deposition, scientific, neurologic, symptoms, booth, exclusive remedy, reliable, workmen's, recommended, respiratory, worker's compensation, recommendations, workplace, hazardous, battery, exposed

LexisNexis(R) Headnotes

Workers' Compensation & SSDI > Coverage > Actions Against Employers > Intentional Misconduct

Workers' Compensation & SSDI > Remedies Under Other Laws > Exclusivity > Exceptions
[HN1] Miss. Code Ann. § 71-3-9 (2000) provides, in part, that the liability of an employer to pay compensation shall be exclusive and in place of all other liability of such employer to the employee. However, based upon the statutory requirement that the "injury" be "accidental" to be compensable under the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., the Mississippi Supreme Court has found that some intentional torts are outside the scope of the exclusivity provision in § 71-3-9. Miss. Code Ann. §§ 71-3-3(b), 71-3-7. The Act does not bar an employee from pursuing a common law remedy against his employer for an injury caused by his employer's wilful and malicious act. Where an injury is caused by the willful act of an employee acting in the course and scope of his employment and in the furtherance of his employer's business, the Act is not the exclusive remedy available to the injured party. This limitation on the Act's exclusivity reflects the public policy that certain courses of conduct (intentional torts) are so shockingly outrageous and beyond the bounds of civilized conduct that the person responsible should not be rewarded with tort immunity.

Workers' Compensation & SSDI > Coverage > Actions Against Employers > Intentional Misconduct
Workers' Compensation & SSDI > Remedies Under Other Laws > Exclusivity > Exceptions
[HN2] With regard to the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., a mere willful and malicious act remains insufficient to give rise to the exception under the Act. Reckless or grossly negligent conduct is not enough to remove a claim from the exclusivity of the Act. The employee also must establish that the egregious act was accompanied by an "actual intent to injure" in order to except the Act's grant of exclusivity. Thus, Mississippi is in concurrence with an overwhelming majority of states in requiring an "actual intent to injure" the employee.

Civil Procedure > Appeals > Standards of Review > De Novo Review
Workers' Compensation & SSDI > Coverage > General Overview
[HN3] The applicability of the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., is a question of law. This Court reviews questions of law de novo.

Workers' Compensation & SSDI > Coverage > Actions Against Employers > Intentional Misconduct
Workers' Compensation & SSDI > Remedies Under Other Laws > Exclusivity > Exceptions
[HN4] With regard to the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., certain intentional torts are outside the scope of the exclusivity provision contained in Miss. Code Ann. § 71-3-9 (2000). Where an injury is caused by the willful act of an employee acting in the course and scope of his employment and in the furtherance of his employer's business, the Act is not the exclusive remedy available to the injured party. The Act does not bar an employee from pursuing a common law remedy against his employer for an injury caused by his employer's wilful and malicious act. Mississippi law clearly provides that certain intentional torts lie beyond the scope of the Act's exclusivity.

Workers' Compensation & SSDI > Coverage > Actions Against Employers > Intentional Misconduct
Workers' Compensation & SSDI > Remedies Under Other Laws > Exclusivity > Exceptions
[HN5] With regard to the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., a mere willful and malicious act remains insufficient to give rise to the exception under the Act. Reckless or grossly negligent conduct is not enough to remove a claim from the exclusivity of the Act. Before recovery may be had for the specific injuries and/or diseases which the plaintiffs claim, there must be proof of actual intent to injure by the employer.

Workers' Compensation & SSDI > Coverage > Actions Against Employers > Intentional Misconduct
Workers' Compensation & SSDI > Remedies Under Other Laws > Exclusivity > Exceptions
[HN6] With regard to the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., in order for a willful tort to be outside the exclusivity of the Act, the employee's action must be done with an actual intent to injure the employee. It is not enough to destroy the immunity that the employer's conduct leading to the injury consists of aggravated negligence or even that the conduct goes beyond this to include such elements as knowingly permitting hazardous conditions to exist or willfully failing to furnish a safe place to work or knowingly ordering the employee to perform a dangerous job.

Workers' Compensation & SSDI > Coverage > Actions Against Employers > Intentional Misconduct

Workers' Compensation & SSDI > Remedies Under Other Laws > Exclusivity > Exceptions
[HN7] With regard to the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., the employer's conduct may have been reckless, negligent, or grossly negligent, but that is not enough to remove this case as an "intentional tort" from the exclusivity of the Act. The Mississippi Supreme Court holds that the employer's action must be done with an actual intent to injure the employee, and that an intentional tort is an act of intentional behavior designed to bring about the injury.

Workers' Compensation & SSDI > Coverage > Actions Against Employers > Intentional Misconduct
Workers' Compensation & SSDI > Remedies Under Other Laws > Exclusivity > Exceptions
[HN8] With regard to the intentional tort exception to the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., to be deemed intentional, the employer's acts or inaction must be designed to bring about the injury.

Civil Procedure > Appeals > Standards of Review > Substantial Evidence > General Overview
[HN9] "Substantial evidence" has been defined as information of such quality and weight that reasonable and fair-minded jurors in the exercise of impartial judgment might have reached different conclusions.

Evidence > Testimony > Experts > Admissibility
[HN10] Under Miss. R. Evid. 702, trial courts are charged with being gatekeepers in evaluating the admissibility of expert testimony. The Mississippi Supreme Court is confident that the learned trial judges can and will properly assume the role as gatekeeper on questions of admissibility of expert testimony. Accordingly, the trial judge has the sound discretion to admit or refuse expert testimony; an abuse of discretion standard means the judge's decision will stand unless the discretion he used is found to be arbitrary and clearly erroneous. The Supreme Court performs only the comparatively narrow analysis of whether the district court's determination that the opinion was sufficiently grounded in "good science" to assist the jury constituted an abuse of that court's discretion.

Evidence > Testimony > Experts > General Overview
Evidence > Testimony > Experts > Admissibility
[HN11] Miss. R. Evid. 702 states: if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the witness has applied the principles and methods reliably to the facts of the case.

Evidence > Testimony > Experts > General Overview
Evidence > Testimony > Experts > Admissibility
[HN12] The trial judge must ensure that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands. This rule makes it necessary for a trial court to apply a two-pronged inquiry when evaluating the admissibility of expert testimony: (1) is the witness qualified; and (2) is the testimony relevant and reliable?

Evidence > Testimony > Experts > Daubert Standard
[HN13] In Daubert v. Merrell Dow Pharms., Inc., the United States Supreme Court set out four non-exclusive factors to aid in the determination of whether the methodology is reliable. They are: (1) whether the theory or technique has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the method used and the existence and maintenance of standards controlling the technique's operation; and (4) whether the theory or method has been generally accepted by the scientific community. This approach is a flexible one. Its overarching subject is the scientific validity -- and thus the evidentiary relevance and reliability -- of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

Evidence > Scientific Evidence > General Overview
Evidence > Testimony > Experts > General Overview

[HN14] With regard to expert testimony, "scientific" implies a grounding in the methods and procedures of science.

Evidence > Testimony > Experts > General Overview
[HN15] With regard to expert testimony, "knowledge" applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truth on good grounds. Of course, it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty. Furthermore, in order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method.

Civil Procedure > Appeals > Standards of Review > Abuse of Discretion
Evidence > Procedural Considerations > Rulings on Evidence
[HN16] In Mississippi, only if the circuit judge abused his discretion in an evidence ruling, acting in an "arbitrary and clearly erroneous" manner, will the Mississippi Supreme Court find error.

Evidence > Testimony > Experts > General Overview
[HN17] With regard to expert testimony, while case-study review is certainly an accepted methodology, trial courts still must be certain that the content of those case studies is relevant to the facts at hand.

Torts > Negligence > Causation > General Overview
[HN18] Under some circumstances, a strong temporal connection is powerful evidence of causation.

Civil Procedure > Trials > Jury Trials > Jury Instructions > General Overview
[HN19] In Mississippi, in reviewing the grant or denial of jury instructions, the Mississippi Supreme Court has stated that reviewing courts are required to review all of the instructions as a whole. No instruction should be reviewed in isolation. When analyzing the grant or refusal of a jury instruction, two questions should be asked: Does the instruction contain a correct statement of law and is the instruction warranted by the evidence? Defects in specific instructions will not mandate reversal when all of the instructions, taken as a whole fairly -- although not perfectly -- announce the applicable primary rules of law. The Supreme Court will not hesitate to reverse if the instructions, when analyzed in the aggregate, do not fairly and adequately instruct the jury.

Workers' Compensation & SSDI > Coverage > Actions Against Employers > Intentional Misconduct
Workers' Compensation & SSDI > Remedies Under Other Laws > Exclusivity > Exceptions
[HN20] In Mississippi, the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., is exclusive absent an actual intent to injure the employee.

Workers' Compensation & SSDI > Coverage > Actions Against Employers > Intentional Misconduct
Workers' Compensation & SSDI > Remedies Under Other Laws > Exclusivity > Exceptions
[HN21] With regard to whether a claim is exemption for the Mississippi Workers' Compensation Act, Miss. Code Ann. § 71-3-1 et seq., as an intentional tort, it is well settled that intent may be shown by circumstances.

Civil Procedure > Trials > Jury Trials > Jury Instructions > General Overview
[HN22] The law requires all jury instructions to be read together. The instructions must be taken together and be construed as a whole, one as modifying, explaining or qualifying another; and, if the instructions taken as a whole correctly announce the law applicable to the case, a reviewing court will not reverse the judgment because of an imperfect single instruction. Where it may be fairly charged that one or more instructions may have been confusingly worded, a reviewing court should not reverse if other instructions clear up the confusing points. Defects in specific instructions do not require reversal where all instructions taken as a whole fairly -- although not perfectly -- announce the applicable primary rules of law.

Civil Procedure > Trials > Jury Trials > Jury Instructions > General Overview
[HN23] A conflict between jury instructions does not justify reversal, if the evidence overwhelmingly supported the plaintiffs' claims and does not result in a miscarriage of justice. In short, the conflict in the evidence made the jury the judges of what the truth was with reference thereto, and courts are unable to say that the jury reached the wrong result.

Civil Procedure > Remedies > Damages > Punitive Damages
Torts > Damages > Punitive Damages > General Overview
[HN24] The primary purpose of punitive damages is to punish the wrongdoer and deter similar misconduct in the future by the defendant and others. Miss. Code Ann. § 11-1-65(1)(e) (2002). Punitive damages may not be awarded if the claimant does not prove by clear and convincing evidence that the defendant against whom punitive damages are sought acted with actual malice, gross negligence which evidences a willful, wanton or reckless disregard for the safety of others, or committed actual fraud. Miss. Code Ann. § 11-1-65(1)(a) (2002). Punitive damages are only appropriate in the most egregious cases so as to discourage similar conduct and should only be awarded in cases where the actions are extreme. The trial court is the gatekeeper for the issue of whether punitive damages, in cases involving both intentional and non-intentional torts, should be submitted and considered by a jury.

Civil Procedure > Remedies > Damages > Punitive Damages
Civil Procedure > Appeals > Standards of Review > Abuse of Discretion
Torts > Damages > Punitive Damages > General Overview
[HN25] An abuse of discretion standard is implemented when a reviewing court reviews the trial court's decision of whether a case warrants punitive damages to be sent to the trier of fact.

Civil Procedure > Remedies > Damages > Punitive Damages
Civil Procedure > Appeals > Standards of Review > De Novo Review
Torts > Damages > Punitive Damages > Award Calculations > Appellate & Posttrial Review
[HN26] The proper assessment of punitive damages under Miss. Code Ann. § 11-1-65(3) is a question of law, to be reviewed by the Mississippi Supreme Court de novo.

Civil Procedure > Remedies > Damages > Punitive Damages
Torts > Damages > Punitive Damages > Award Calculations > Factors
[HN27] Miss. Code Ann. § 11-1-65(3) (2002) provides, in part, that: (a) In any civil action where an entitlement to punitive damages shall have been established under applicable laws, no award of punitive damages shall exceed the following: (v) $ 5 Million Dollars for a defendant with a net worth of more than $ 50 Million Dollars but not more than $ 100 Million Dollars; or (vi) Four percent of the defendant's net worth for a defendant with a net worth of $ 50 Million Dollars or less. (b) For the purposes of determining the defendant's net worth in paragraph (a), the amount of the net worth shall be determined in accordance with Generally Accepted Accounting Principles.

COUNSEL: FOR APPELLANT: JAMES LAWTON ROBERTSON, JENNIFER HUGHES SCOTT, ELIZABETH G. HOOPER, BRIDGET E. KOBS.

FOR APPELLEES: HEBER S. SIMMONS, III, WILLIAM MELVIN ROSAMOND, DOUGLAS G. MERCIER, JOHN ROBIN BRADLEY, JR.

JUDGES: WALLER, C.J., CARLSON, P.J., RANDOLPH, LAMAR AND PIERCE, JJ., JOIN THIS OPINION. GRAVES, PRESIDING JUSTICE, SPECIALLY CONCURRING. DICKINSON, JUSTICE, SPECIALLY CONCURRING.

OPINION BY: RANDOLPH

OPINION

[*219] ON MOTION FOR REHEARING

NATURE OF THE CASE: CIVIL - WORKERS' COMPENSATION

EN BANC.

RANDOLPH, JUSTICE, FOR THE COURT:

P1. The motion for rehearing filed by Franklin Corporation is denied. The previous opinions of this Court are withdrawn and these opinions are substituted therefor.

P2. Today we are presented with the latest conflict in the ongoing legal struggle between industry and labor regarding compensation and medical indemnity for employees injured in the workplace. The appellees/employees seek to expand the scope of egregious conduct excluded from the Mississippi Workers' Compensation Law ("Act") to include acts which are "substantially certain" to cause injury to the employee. **[**2]** Not surprisingly, the appellant/employer clamors for the opposite, requesting that this Court overrule ***Miller v. McRae's, Inc.,*** 444 So. 2d 368 (Miss. 1984), and its progeny and retreat from these decisions, which exclude employers' tort immunity for certain egregious acts accompanied by an "actual intent to injure" the employee. After due consideration and deliberation, this Court chooses to do neither. The constitutionally delineated forum for change is the Mississippi Legislature, not this Court. We find that the correct balance is in place and so shall remain, unless the Legislature should decide otherwise.

P3. In the case *sub judice,* Pauline Tedford, Lora Smith, Judy Haire, and Samantha Mixon ("Plaintiffs") filed suit alleging multiple claims against multiple defendants, including claims against their employer, Franklin Corporation, for battery and intentional infliction of emotional distress arising from injuries sustained in the course and scope of their employment. Franklin Corporation filed a "Motion to Dismiss" and a "Motion for Summary Judgment," contending that the exclusive remedy for the Plaintiffs was provided by the Act. After due consideration by the circuit court, the **[**3]** trial judge denied the relief sought and set the matter for trial. At trial, the jury found in favor of the Plaintiffs, awarding both compensatory and punitive damages. Thereafter, the circuit court denied Franklin Corporation's "Motion for J.N.O.V., or in the Alternative, for New Trial or Remittitur," but reduced the punitive damage award. From those rulings, Franklin Corporation appeals.

HISTORICAL BACKGROUND

P4. The demand of labor for the protection of workers' compensation laws is well-established. *See* O.W. Holmes, *The Path of the Law,* 10 Harv. L. Rev. 457, 466-67 (1897) ("[s]ince the last words were written, I have seen the requirement of such insurance put forth as part of the programme of one of the best known labor organizations."). This was largely in response to the denial of employer indemnity in the majority of workplace accidents, due to the lack of proof of employer fault [1] or employer defenses such as contributory negligence, assumption of risk, and the fellow-servant rule. *See* Downey, *History of Work Accident Indemnity in Iowa* at 5, 17, 78. The prevailing view of labor was that:

> [a]n indemnity system which tediously grinds out such results as these is no better than a **[**4]** gamble -- a gamble which awards a few prizes to injured persons and deludes all other injured persons **[*220]** into thinking they are going to draw prizes, too, when, as a matter of fact, they are going to draw blanks; a gamble which makes the employer pay preposterous sums to certain people and so prevents him from paying reasonable sums to all. It is on the same level as faro.

Id. at 80 (internal quotation marks omitted). *See also* P.V. Fishback & S.E. Kantor, *A Prelude to the Welfare State: The Origins of Workers' Compensation,* 11 (University of Chicago 2000) ("[r]eformers decried the common law system" for uncompensated injuries, "uncertain and unequal payouts," high transactional costs, and delay). By the early 1900s, President Theodore Roosevelt included "comprehensive workmen's compensation acts" within his progressive program for economic reform, the "Square Deal." T. Roosevelt, *The New Nationalism* (Aug. 31, 1910), in 13 *The Annals of America* 250, 253 (Encyclopedia Britannica, Inc. 1976).

> 1 For example, "[e]very mechanical employment has a predictable hazard: of a thousand men who climb to dizzy heights in erecting steel structures a certain number will fall to death, and of a thousand **[**5]** girls who feed metal strips into stamping machines a certain number will have their fingers crushed." E.H. Downey, *History of Work Accident Indemnity in Iowa* 5 (Benjamin F. Shambaugh, ed., State Historical Society of Iowa 1912).

P5. The subsequent "advent of state workers' compensation laws after 1910 marked the removal from the tort system of most suits by injured workers against employers." Note, *Exceptions to the Exclusive Remedy Requirements of Workers' Compensation Statutes,* 96 Harv. L. Rev. 1641, 1641 (1983). In fact, "[b]etween 1911 and 1920, 41 states enacted workers' compensation statutes." *Id.* at 1641 n.1 (citing E.H. Downey, *Workmens' Compensation,* 162 n.18 (1924)). Initially, some courts deemed such statutes to be so radical as to constitute

an unconstitutional deprivation of the employer's property without due process of law. *See* ***Ives v. South Buffalo Ry.,*** 201 N.Y. 271, 94 N.E. 431 (1911); J.C. Satterfield, *An Introduction to the Mississippi Workmens' Compensation Act,* 20 Miss. L.J. 27, 31 (1948) ("three of the four acts adopted prior to 1911 were declared unconstitutional . . ."). However, after their widespread acceptance had been established:

> Mississippi became the last **[**6]** state to adopt a system of Workmen's Compensation. This type of legislation is generally viewed as a compromise between the interest of labor and business. Because of the exclusive nature of the remedy labor surrenders the right to assert a common law tort action along with the attendant possibility of achieving punitive damages. In exchange it receives assurance that an award is forthcoming. Industry surrenders its three major common law defenses: contributory negligence, assumption of risk, and the fellow servant rule. In exchange it receives the knowledge that there will be no outrageously large judgments awarded to injured employees. [2] The entire system was designed to insure that those injured as a result of their employment would not be reduced to a penniless state and thereby become dependent on some form of governmental public assistance.

Miller, 444 So. 2d at 370. *See also* ***Stevens v. FMC Corp.,*** 515 So. 2d 928, 932 (Miss. 1987) (quoting ***Sawyer v. Head,*** 510 So. 2d 472, 477 (Miss. 1987)) ("[b]y the exchange, the remedy of workers' compensation benefits, insofar as the right of the employee **[*221]** against [the] employer and fellow employees are concerned, is abrogated."); John R. Bradley **[**7]** & Linda A. Thompson, *Mississippi Workers' Compensation* § 1:1 (2007) ("[t]hus, compensation by the employer for most employment injuries has been taken out of the tort law and placed within a separate branch of law -- worker's compensation, a no-fault plan [3] handled in an administrative setting by an executive branch agency."). Ultimately, the workers' compensation system lends valuable predictability to both employees and employers. Employees receive guaranteed compensation for covered injuries, bypassing the civil-litigation risks of either no recovery or uncollectible judgments against insolvent employers. Employers receive fixed levels of potential liability which they can anticipate and treat as a general "cost of doing business."

2 The mutual benefit of the workers' compensation system in Mississippi was described as follows:

> both the employers and employees will be materially benefitted by this legislation. The psychological effect upon industries coming into Mississippi is good, and it appears that the employers on the average will reap a financial saving and the employees a financial benefit. On the whole the Act is fair and workable, and compares favorably with the statutes now **[**8]** in existence in the other states.

Satterfield, *An Introduction to the Mississippi Workmens' Compensation Act,* 20 Miss. L.J. at 48.

3 These "no-fault" aspirations of the Act have been largely met, as statistics from 2007 reveal that more than seventy-eight percent of lost-time cases in Mississippi are uncontested. *See* Mississippi Workers' Compensation Commission, *Annual Report Cumulative Information Tables,* at http://www.mwcc.state.ms.us/info/_annreportcumu.asp ("Total Claims by Year") (last visited Sept. 1, 2009).

P6. [HN1] Mississippi Code Section 71-3-9 provides, in part, that "[t]he liability of an employer to *pay compensation* shall be *exclusive* and in place of all other liability of such employer to the employee . . . ." Miss. Code Ann. § 71-3-9 (Rev. 2000) (emphasis added). However, based upon the statutory requirement that the "injury" be "accidental" to be compensable under the Act, *see* Mississippi Code Sections 71-3-3(b), 71-3-7, this Court has found that some intentional torts are outside the scope of the exclusivity provision in Mississippi Code Section 71-3-9. Miss. Code Ann. §§ 71-3-3(b), 71-3-7 (Rev. 2000). *See* ***Royal Oil Co. v. Wells,*** 500 So. 2d 439, 442 (Miss. 1986) ("the [Act] **[**9]** does not bar an employee from pursuing a common law remedy against his employer for an injury caused by his employer's wilful and malicious act"); ***Miller,*** 444 So. 2d at 371 ("where an *injury* is *caused by* the *willful act of an employee acting in the course and scope of his employment and in the furtherance of his employer's business,* the [Act] is *not* the *exclusive remedy* available to the injured party") (emphasis added). This limitation on the Act's exclusivity "reflects the public policy that certain courses of conduct (intentional torts) are so shockingly outrageous and beyond the bounds of civilized conduct that the person responsible should not be rewarded with tort immunity." Bradley & Thompson, *Mississippi Workers' Compensation* at § 11:8.

P7. In ***Peaster v. David New Drilling Co.,*** 642 So. 2d 344 (Miss. 1994), this Court held that [HN2] "[a] mere willful and malicious act remains insufficient to give rise to the exception under the Act." ***Id.*** at 348. *See also* ***Blailock v. O'Bannon,*** 795 So. 2d 533, 535 (Miss. 2001) ("[r]eckless or grossly negligent conduct is not

enough to remove a claim from the exclusivity of the Act."). The employee also must establish that the egregious act was accompanied **[**10]** by an "actual intent to injure" in order to except the Act's grant of exclusivity. *See* ***id.; Peaster,*** 642 So. 2d at 348-50; ***Griffin v. Futorian Corp.,*** 533 So. 2d 461, 464 (Miss. 1988). Thus, Mississippi is in concurrence with an overwhelming majority of states in requiring an "actual intent to injure" the employee. *See* 6 Arthur Larson, *Larson's Workers' Compensation Law* § 103.01 nn.4-6, § 103.04[1] (2008).

P8. Having set forth the law in existence at the time the subject events unfolded, we turn to the specific facts developed and stipulated in this case.

[*222] FACTS

P9. Franklin Corporation is a furniture manufacturer located in Houston, Mississippi. In January 1999, George Parker, an employee of Mid-South Adhesives, Inc. ("Mid-South"), made a presentation to Franklin Corporation regarding Mid-South's Soft Seam Adhesive ("Soft Seam") product. During the presentation, Parker provided Franklin Corporation with a May 22, 1998, "Material Safety Data Sheet" ("MSDS") [4] and warning label for Soft Seam. The MSDS disclosed that Soft Seam contained a neurotoxin known as propyl bromide ("1-BP") and included a "[m]anufacturer's recommended exposure limit" of no more than 100 parts per million ("ppm"). **[**11]** Under "Section VI - Health Hazard Data," the MSDS further declared that the product was an "[i]rritant to upper respiratory tract. Symptoms may include coughing, headache, nausea, dizziness, wheezing, laryngitis, shortness of breath and vomiting. These short term acute [e]ffects of exposure are noticed above 150 to 250 ppm." Regarding symptoms of exposure to the skin, the MSDS revealed a risk of "[i]rritation, defatting of skin, and dermatitis." Furthermore, "[p]rolonged exposure to [1-BP] can cause adverse effects to the liver, kidney, central nervous system and respiratory system." "Section VII - Precautions for Safe Handling and Use" included, "Warning! Vapors harmful! Use only with adequate ventilation!" "Section VIII - Control Measures" provided:

> [a]bove PEL/TLV ["permissible exposure limit/threshold limit value"], an approved organic vapor type respirator is acceptable. Approved self-contained breathing apparatus or air line respirator with full face piece, is required for vapor concentrations above 1000 ppm and for spills and emergencies.
>
> . . . .
>
> Do not use in confined space. Open doors and/or windows. Use ventilation to maintain employee exposure levels below the manufacturers **[**12]** recommended exposure limit.
>
> . . . .
>
> Avoid contact with skin and avoid breathing vapors.

By June 30, 1999, and later, on July 31, 2002, the PEL/TLV in the MSDS for Soft Seam was reduced to "100 ppm." As stipulated by the parties, Franklin Corporation:

> was aware of the contents of the MSDS and warning label and the language relating to ventilation, [5] respiratory, skin and eye protection requirements for use of [Soft Seam] as well as the potential harmful effects to humans for prolonged, unprotected exposure to [1-BP] at levels that exceeded the applicable exposure levels.

4 According to John T. Gordon, a "Technical Director Chemist" responsible for creating the MSDS for Mid-South, "[t]he purpose of an MSDS sheet is to inform workers of hazardous chemicals in the workplace."

5 Parker discussed ventilation with Don Livingston, vice-president and director of purchasing at Franklin Corporation, who replied "it was going to be awfully expensive." Livingston denied this statement and testified that "Parker never told me that it needed ventilation."

P10. The parties stipulated that Franklin Corporation had purchased and used Soft Seam "on its glue line in the production and manufacture of furniture[,]" **[**13]** beginning in 1999. According to Livingston, Soft Seam provided a significant cost savings to Franklin Corporation, as the glue line was reduced from three shifts to one shift. However, Franklin Corporation decided not to install mechanical ventilation **[*223]** exhausts outside the building on the glue line. [6] [7]

6 The building did have a downdraft system which exhausted air outside the booths in which glue-line employees worked, along with roof fans.

7 Linda Bean, a glue-line employee in 1999, testified that another glue-line employee had directly confronted Hassell Franklin, the president, CEO, and principal shareholder of Franklin Corporation, in the old building about the need for ventilation. She further testified that Franklin had responded that he was not going to spend any more money as they would be moving into the new building soon.

P11. In September 2000, Franklin Corporation moved its poly department, including the glue line, into a new, 90,000-square-foot building. Although the facility had air conditioning, no mechanical ventilation was installed exhausting outside the building. [8] On February 7, 2001, Franklin Corporation temporarily ceased purchasing Soft Seam due to a change in its **[**14]** production methods. On April 10, 2001, an "Industrial Hygiene Evaluation" was performed by industrial hygienist Kevin C. Housman on behalf of Franklin Corporation's workers' compensation insurer, Liberty Mutual Insurance Company, addressing "noise reduction and hearing protection, wood dust exposure, and exposure to organic vapors including but not limited to [1-BP] on the glue line." The May 8, 2001, report issued by Housman notably found that:

> [m]ost exposures were either below our lab's quantifiable limits and/or below the corresponding TLVs, except for Ms. [Linda] Bean's exposure to [1-BP]. Her 8-hr TWA ["time-weighted average"] exposure was calculated to be 75 ppm. [9] *This particular chemical has a manufacturer's recommended workplace exposure limit of 10 to 25 ppm. Thus, substitution of this gluing agent currently in use at the Polyfoam Plant is strongly encouraged. Ventilation of this process should be considered a secondary control and is also recommended.* [10]

(Emphasis added.) Scott Shempert, the safety director at Franklin Corporation at all relevant times, wrote a note on his copy of Housman's report providing "contacted [Livingston] 5-16-01[,] said he would look into it." No **[**15]** glue-line employees at Franklin Corporation were notified of the results reported or the recommendations provided in Housman's report concerning 1-BP. None of the ventilation or respiratory-protection recommendations in Housman's report were implemented by Franklin Corporation. [11] On January 30, 2002, Franklin **[*224]** Corporation resumed purchasing Soft Seam from Mid-South. On July 31, 2002, the MSDS for Soft Seam was revised to include an "EPA proposed acceptable exposure limit" of 25 ppm regarding 1-BP. [12]

8 According to Frank Casteel, an electrician in the maintenance department at Franklin Corporation, John Lyles, the vice-president of manufacturing at Franklin Corporation at all relevant times, instructed him not to run electricity to the downdraft system in the new building.

9 Specifically, Housman measured 28 ppm over 161 minutes and 110 ppm over 216 minutes.

10 Other pertinent recommendations by Housman included the implementation of a respiratory protection program, the installation of a chemical review process regarding MSDSs, future air monitoring, and informing glue-line employees of the present exposure levels.

11 Shempert maintained that prior to July 31, 2002, the MSDS for Soft Seam **[**16]** provided that the "[m]anufacturer's recommended exposure limit" was 100 ppm, which was greater than the 75 ppm time-weighted average in Housman's report. On that basis, and despite Housman's reference to 10-25 ppm as the "manufacturer's recommended workplace exposure limit," Franklin Corporation consciously chose not to inform glue-line employees of the exposure risks associated with 1-BP or to implement the recommendations related to 1-BP included in Housman's report.

12 However, according to Gordon, the "EPA does not regulate the workplace." Shempert added that "the fact that it was a proposed acceptable exposure limit did not put it in place, in my opinion as the safety director [at Franklin Corporation]." On the other hand, the expert testimony of occupational toxicologist Gaku Ichihara, M.D., was that the EPA regulates 1-BP "because . . . [1-BP] is the alternative to the freon or other ozone-depleting solvents."

P12. Regarding the Plaintiffs, their employment on the glue line began as follows: Tedford -- April 12, 1999; Haire -- September 16, 2002; Mixon -- September 15, 2003; and Smith -- October 22, 2003. Their wages varied between eight and nine dollars per hour. On the glue line, **[**17]** the Plaintiffs would use "a pressurized spray system to apply [Soft Seam] to foam used in the manufacture of furniture produced and sold by Franklin

Corporation." [13] In September 2003, new wooden spray booths for the glue-line employees were constructed. The new booths were draped in plastic and were primarily occupied by Plaintiffs Smith, Mixon, and Haire. [14] According to glue-line employee Vicki Veazey:

> when you was in those booths, . . . the scent was too strong because it could not escape. Naturally, if you had had ventilation or even the top was open, it would have been better . . ., but at the time the . . . booths had the little plastic tops across the top of them. [15]

Shempert did not consider the installation of these new booths to be a manufacturing change, and thus did not request updated air testing on the glue line.

13 The parties stipulated that the Plaintiffs' entire exposure to 1-BP occurred at Franklin Corporation, while in the course and scope of their employment.

14 The booth in which Tedford worked was slightly larger and did not have a plastic cover over the top.

15 By Haire's description, "most of the vapors would come right back into you. It didn't have nowhere to go."

P13. **[**18]** Throughout the Plaintiffs' employment, numerous glue-line employees testified to making repeated complaints to supervisors and upper management about the ill symptoms they were experiencing, the need for ventilation, and the need for protective gear. The adverse symptoms experienced by glue-line employees frequently were exacerbated when operating in the new booths.

P14. The Plaintiffs testified that their complaints routinely were dismissed or ignored by supervisors and upper management. [16] Tedford testified that when she initially complained to James R. Clark, the superintendent of the poly department from January 1999 until September 2003, "he told me that it wasn't the glue. They had been using it for years." Later, Clark informed Tedford that Franklin Corporation was not "going to ventilate it because of the money." Mixon testified that Jeff Clements, the superintendent of the poly department beginning in September 2003, told her that ventilation "was too expensive. It would probably never happen." [17] **[*225]** When Tedford complained to Jimmy Pumphrey, a superintendent in the poly department, "[h]e just played it off. [He said] [t]here's nothing wrong with you. Go on back in your booth **[**19]** and go to work." [18] Casteel testified that when one employee complained to vice-president Lyles that the glue was "burning our hands and making us dizzy, . . . he just smiled and walked off."

16 For instance, according to Veazey, when she informed her supervisor that the glue was causing her headaches, she was simply told to take some Tylenol.

17 According to Smith, in response to her request for ventilation, Clements "looked at the ceiling, and he said, there's no way to put ventilation in here. He said that . . . it was too expensive and they couldn't afford it." Haire testified that Clements told her that "he had already asked and they told [him] that there was no money appropriated for it at the time."

18 Mixon and glue-line employees Jackie Davidson and Lynn Byars testified to similar responses from Pumphrey. According to Smith, Pumphrey would occasionally "laugh at us, saying y'all are high. I believe that glue has gone to y'all's head or something." Casteel heard Pumphrey tell one employee, "[e]ither do the job or go home." Smith further testified that Pumphrey's response to her request for ventilation was "[t]hat there will never be, and [he] walk[ed] away."

P15. According to Clark: **[**20]** [19]

> I had complained to [Livingston] about the fumes and problems being reported by the workers in the glue line. [20] He stated at that time that he knew that Franklin [Corporation] needed to install a ventilation system on the glue line, but that he didn't believe that Hassell Franklin had decided to "let me put a hole in the ceiling" to install such a ventilation system. [21]

When Clark informed Lyles of further complaints by glue-line employees, Lyles "told [him] that [he] was not doing a good enough job of convincing the Plaintiffs that their complaints were 'all in their heads' and that I had to be a 'better salesman' to convince the Plaintiffs that their complaints were not real." [22] Clark additionally provided that in a meeting with Franklin and Lyles, Franklin informed him:

> that he "was not going to throw money at this problem." He said that no ventilation system would be installed as the company was not going to spend money on a glue line ventilation system for an adhesive that was probably not going to be allowed much longer anyway, and that it would be a waste of money . . . regardless of any complaints from the workers on the glue line. [23]

Moreover, Clark testified that Franklin **[**21]** and Lyles had maintained that "we're not going to suck the air-conditioning out through holes in the ceiling." According to Clark, Franklin had referred to glue-line employees as performing a "grade two job" [24] and that "if they don't like it . . . they can go to work somewhere else." Furthermore, Clark testified that Lyles had stated "there are people lined up out there for jobs; if they start dropping like flies, or something in that order, we can replace them today . . . ."

19 This Court notes that Clark did not testify at trial. His testimony, derived from his November 2, 2004, affidavit and November 2, 2005, deposition, was, however, considered by the circuit court in ruling on Franklin Corporation's "Motion for Summary Judgment." This Court considers Clark's testimony only for purposes of assessing that ruling. *See* P 33 *infra.*

20 Livingston denied having knowledge of any employee complaints prior to January or February 2004.

21 Jim Tidwell, a supervisor at Franklin Corporation in 1999 and 2000, testified that he personally had observed Franklin discuss ventilation and then refuse its installation.

22 By contrast, Lyles asserted that he did not become aware of complaints by glue-line **[**22]** employees until mid-February 2004.

23 Franklin denied stating that he would not install ventilation because it was too expensive, and testified that he was unaware of any ventilation complaints prior to 2004. According to Franklin, when he learned of the problem, "we installed the ventilation system."

24 Clark stated that a "grade two job" means "the lowest level in the house, anybody can do it."

[*226] P16. The Plaintiffs further assert that they were not provided with adequate protective gear. Smith testified that she asked Pumphrey for respiratory masks "[a]t least once a week[,]" but that "[t]hey just always said they would get it, and it never came." [25] Following a spill of approximately 330 gallons of Soft Seam in September 2000, Clark testified that he and Pumphrey were "instructed by . . . Lyles to clean up the spill with no ventilation, protective clothing or protective respiratory equipment." When Clark experienced dizziness and nausea, he claims that Lyles "told me to go outside and take a break, but do whatever it took to get it cleaned up."

25 According to Shempert, however, white paper dust masks manufactured by 3M were always available to glue-line employees. On this subject, Clements **[**23]** testified that glue-line employee Norma Pettit was the only employee from whom he had heard complaints. Thereafter, Clements stated that he gave her a face mask.

P17. Following complaints of Tedford, after her review of the MSDS, Clark stated that Lyles directed Pumphrey "to keep all information away from employees . . . . In accordance with these instructions, all MSDS[s] were thereafter removed from the [Soft Seam] containers by [Pumphrey] . . . ." [26] Relatedly, numerous employees testified that the MSDSs were removed from the glue drums. [27] In one instance, when Smith asked Pumphrey where the MSDS was, "he said, there's not one."

26 An updated MSDS sheet was attached to the glue drum of every shipment of Soft Seam.

27 Conversely, Pumphrey testified that when glue-line employees began taking the MSDSs off the glue drums, "I started taking them off and putting them in the office."

P18. On January 27, 2004, Smith was placed on medical leave by Franklin Corporation, and subsequently was admitted to the hospital on January 29, 2004. Smith reported symptoms to her treating physician, Dr. Kevin Merigian, of "numbness and tingling from waist to toes, nervous -- shakin[g], headache, dizziness, **[**24]**

nausea, vomiting -- cramping in toes, feet and . . . calf." On February 9, 2004, Haire was placed on medical leave by Franklin Corporation, and then was admitted to the hospital on February 12, 2004. Haire stated symptoms to Dr. Merigian of "stinging in feet and numbness from waist to my feet." On February 14, 2004, Mixon was admitted to the hospital after being placed on medical leave by Franklin Corporation that same day. Mixon reported symptoms to Dr. Merigian of "numbness in butt, lower back, legs, and feet; feels like they are asleep and tingling; vomiting; headaches; dizziness; trouble breathing." [28] On April 21, 2004, Tedford was placed on medical leave by Franklin Corporation, and thereafter received medical treatment on April 22, 2004. Tedford experienced symptoms of leg numbness, heaviness in her lower extremities, and difficulty walking. [29]

28 On April 12, 2004, Mixon returned to Franklin Corporation and began working in the backfilling department, where she remained employed at the time of trial.

29 Nearly three years later, on March 17, 2007, Dr. S.H. Subramony, a board-certified neurologist, examined the Plaintiffs and found permanent residual neurological deficits causing **[**25]** continued motor difficulties in Tedford and "significant disability" in Haire and Smith. At trial, Dr. Merigian opined, to a reasonable degree of medical certainty, that the chances of Smith's condition improving were "quite poor" and that Haire's and Tedford's conditions "will not improve[.]"

P19. On February 16, 2004, Franklin Corporation placed its final order for Soft Seam. That same day, Livingston informed **[*227]** Parker that several glue-line employees (specifically, Smith, Haire, and Mixon) had been hospitalized, and that further air testing was necessary. On February 17, 2004, Parker conducted an air-sampling test on the glue line at Franklin Corporation. This was only the second air test performed on the glue line in the five years since Franklin Corporation had begun using Soft Seam. According to Tedford, glue-line operations were slow that day. Parker's subsequent letter to Shempert and Livingston provided that "[v]enting the exhaust through the roof with mechanical air assisted motors is required to meet *the 25 PPM standard* in the work area." (Emphasis added.) On February 23, 2004, an industrial hygienist from the Occupational Safety and Health Administration (OSHA) arrived unannounced **[**26]** and tested the air quality on the glue line. Glue-line employees testified that glue-line operations were typical that day. The inspection report from OSHA, issued April 26, 2004, found time-weighted averages of 1-BP of 205 and 219 ppm. According to the report, 219 ppm "is 9 times the [MSDS] recommended level of 25 [ppm] and 43 times the target limit of 5 [ppm] recommended by OSHA Technical Center." [30] The report noted the absence of ventilation, respiratory protection for employees, or sufficient air testing performed by Franklin Corporation. [31]

30 At the time of trial, OSHA had not yet set exposure limits for 1-BP. However, according to Gordon, the American Conference of Governmental Industrial Hygienists set the threshold value limit for exposure to 1-BP at 10 ppm in June 2004.

31 On April 27, 2004, OSHA issued a "Citation and Notification of Penalty" to Franklin Corporation. For the "serious" violation of excessive exposure of glue-line employees to 1-BP, OSHA proposed a $ 3,500 penalty. For the "serious" violation of the absence of employee "training on the hazards on the [S]oft [S]eam adhesive[,]" OSHA proposed a $ 1,125 penalty. On May 19, 2004, an "Informal Settlement Agreement" **[**27]** was reached between Franklin Corporation and OSHA whereby Franklin Corporation "agree[d] to correct the violations" and OSHA amended the penalties to $ 2,000 and $ 500, respectively.

P20. On February 27, 2004, Franklin Corporation began purchasing a new glue containing acetone from Mid-South. On March 10, 2004, new ventilation booths were installed on the glue line at Franklin Corporation and were fully operable. Fabrication and installation of the new ventilation booths by Kline Heating and Air cost $ 11,165. Following installation of ventilation, glue-line employees were instructed on the nature and use of the acetone glue.

P21. From February 16, 2004, until March 10, 2004, Franklin Corporation continued to use Soft Seam without providing additional ventilation or respiratory protection to glue-line employees, and without informing them of the overexposure reported by Parker. According to Shempert, "[m]y position as the corporate representative [32] would be that we would follow the OSHA regulations provided to us by these MSDS, and we did so." Shempert maintained that the absence of recommended exposure limits by OSHA weighed heavily in the decision not to ventilate. Shempert testified **[**28]** that:

> OSHA is the governing body over which workers should be able to come in and have a safe workplace . . . . They don't have an exposure limit. The manufacturer sets 100 [ppm], so that's what I was going on as a secondary measure, but OSHA would take precedence over anything else in any of these.

[*228] By contrast, industrial hygienist John Spencer testified:

> I can't think of [a plant] that was worse[,] to put . . . a group of individuals, into an enclosed area and spray a solvent day in and day out for hours upon hours . . . without any ventilation, without proper respiratory protection is not only [a] violation of a variety of occupational health standards; but it's just, it's difficult for me to explain why someone would do that, especially in light of the complaints that were coming from those individuals conducting that work.

Spencer opined, "if they had followed [Housman's] recommendations and followed [Parker's] recommendations, they would have likely significantly reduced those exposures where it wouldn't have been a harmful level."

32 According to Livingston, however, the ultimate decision on ventilation would have been made by Franklin.

P22. On August 16, 2004, a Complaint was filed **[**29]** in the Circuit Court of Calhoun County by the Plaintiffs, along with Clark, Sandra Darlene Clark, [33] Tommy Tedford, Harold E. Haire, and Joshua Mixon [34] against Franklin, Lyles, Livingston, Clements, Pumphrey, and John Does 1-10 ("Franklin Defendants"), [35] Franklin Corporation, and Mid-South. [36] The causes of action asserted in the Complaint included: breach of warranty, negligence, and negligence per se by Mid-South; misrepresentation, intentional misrepresentation, fraud, [37] and civil conspiracy [38] by Mid-South, Franklin Corporation, and the Franklin Defendants; battery by Franklin Corporation and the Franklin Defendants; and intentional infliction of emotional distress by Mid-South, Franklin Corporation, and the Franklin Defendants. The Complaint added that "the actions of Defendants are so egregious, willful, wanton and **[*229]** malicious in nature that punitive damages are requested . . . ."

33 On May 7, 2007, an "Order of Voluntary Dismissal" was entered by the circuit court as to "all of the claims plead[ed] by Plaintiffs, James R. Clark and Sandra Darlene Clark . . . against all of the Defendants . . . ."

34 Tommy Tedford, Harold E. Haire, Joshua Mixon, and Sandra Darlene Clark claimed **[**30]** losses of consortium.

35 On May 7, 2007, the Plaintiffs agreed to dismiss with prejudice the claims asserted against the individual Franklin Defendants. Per that agreement, "the individual defendants will execute affidavits, the form and content of which have been agreed to by counsel for the individual defendants and counsel for the plaintiffs." The affidavit of each "Franklin Defendant" provided:

> [a]t all relevant times plead [sic] in the Complaint for this civil action, and at all relevant times of my employment with Franklin Corporation to which I testified in my deposition, all of my acts and omissions, *including my intentional acts and omissions, if any,* were in the course and scope of my employment with Franklin Corporation as a management level employee, as a means to accomplish the purposes of my employment, and in furtherance of the business of Franklin Corporation. All of my actions and omissions, *including my intentional acts and omissions, if any,* were authorized and/or ratified by Franklin Corporation.

(Emphasis added.)

36 The Second Amended Complaint, filed in the circuit court on January 26, 2007, added Locke Barkley, Bankruptcy Trustee for Pauline and Tommy Tedford, and **[**31]** Selene Maddox, Bankruptcy Trustee for James and Sandra Darlene Clark, as Plaintiffs. Based upon the May 7, 2007, "Order of Voluntary Dismissal," all claims of the Clarks, by and through Maddox, also were dismissed.

37 On May 25, 2007, the circuit court entered an "Agreed Order and Rule 54(b) Judgment of Dismissal with Prejudice as to Plaintiffs' Intentional/Fraudulent Misrepresentation Claims" against Franklin Corporation and Mid-South.

38 On May 22, 2007, the circuit court entered an "Agreed Order and Rule 54(b) Judgment of Dismissal with Prejudice as to Plaintiffs' Civil Conspiracy Claims" against Franklin Corporation and Mid-South.

P23. On October 21, 2004, Franklin Corporation filed a "Motion to Dismiss," relying on the "exclusive remedy" provision of the Act, Mississippi Code Annotated Section 71-3-9 (Rev. 2000). At the hearing thereon, Circuit Judge Andrew K. Howorth conceded that "[t]his is a tough one." Ultimately, however, the motion was denied as

"the [c]ourt specifically finds that the Plaintiffs have alleged sufficient facts and causes of action, which under the relevant standard of review, satisfy the intentional tort exception to the application of [the Act]." Franklin Corporation **[**32]** subsequently filed a "Petition for Interlocutory Appeal and to Stay Enforcement of Circuit Court Order Pending Appeal" regarding the exclusivity of the Act, which the circuit court granted. This Court initially granted Franklin Corporation's "Petition for Interlocutory Appeal," but thereafter dismissed it as improvidently granted.

P24. On May 19, 2006, Franklin Corporation filed a "Motion for Summary Judgment" in the circuit court, reiterating that the Plaintiffs' "exclusive remedies are pursuant to the [Act] . . . ." At that hearing, the circuit judge stated:

> while I'm not aware of any law on this, I think intent can be like scienter is in the law. . . . We know that in scienter you knew or should have known; and *I think with intent you either intended it or you were possessed with sufficient facts where you could be deemed to have intended it even if you didn't intend the specific consequences* . . . . That's just kind of my view of the thorniness of this thing.

(Emphasis added.) On that basis, while deeming the matter to be "very close," the circuit judge denied the motion, finding there "are genuine issues of fact as to whether or not there was *intent to injure.*" (Emphasis added.)

P25. **[**33]** Following a three-week trial, the jury found in favor of the Plaintiffs on the claims of *battery and intentional infliction of emotional distress* against Franklin Corporation. The "Final Judgment" recited that "[t]he jury found in favor of [Mid-South] on the claim of negligence asserted against it by Plaintiffs." [39] All liability was attributed to Franklin Corporation, and compensatory damages were assessed, as follows: Mixon -- $ 75,000; Tedford -- $ 800,000; Smith -- $ 250,000; Haire -- $ 800,000. [40]

> 39 Thereafter, a "Final Judgment" was entered by the circuit court dismissing the Plaintiffs' claims against Mid-South with prejudice.
>
> 40 The jury awarded no damages to Plaintiffs Tommy Tedford, Harold E. Haire, and Joshua Mixon on their loss-of-consortium claims.

P26. The issue of punitive damages was then presented to the jury, which returned a verdict of $ 7,500,000 for the Plaintiffs against Franklin Corporation. The "Final Judgment" of the circuit court, "upon due consideration of the net worth and financial condition" of Franklin Corporation *at the time the complaint was filed,* concluded that the proper amount of punitive damages to be awarded was $ 1,836,213, pursuant to Mississippi Code Annotated Section 11-1-65(3)(a) **[**34]** (Rev. 2002).

P27. Franklin Corporation subsequently filed a "Motion for J.N.O.V., or in the Alternative, for a New Trial or a Remittitur," and the Plaintiffs filed a "Motion to Reconsider Punitive Damages, to Alter or Amend Final Judgment, for Relief from Final Judgment, or for Other Relief." The Plaintiffs sought amendment of the "Final Judgment":

> **[*230]** by either: a) adjusting and amending that . . . punitive damages figure from $ 1,836,213 to $ 5,000,000 to comport and comply with Miss. Code Ann. Section 11-1-65 (Supp. 2003) by application of the statutory cap to the "net worth" figure of $ 61,543,082 for . . . Franklin Corporation, which was its *"net worth" at the time of trial;* or b) amending and adjusting the punitive damages . . . from $ 1,836,213 to the $ 7,500,000 punitive damages amount awarded by the verdict of the jury without statutory reduction if Miss. Code Ann. Section 11-1-65(3)(a-c) (Supp. 2003) is found to be void, unconstitutional and/or inapplicable.

(Emphasis added.) Thereafter, the circuit court entered an "Order Granting Motion to Reconsider Punitive Damages, to Alter or Amend Final Judgment, for Relief from Final Judgment, or for Other Relief," finding that:

> the proper **[**35]** net worth of [Franklin Corporation] to be utilized in the application of the legislative caps is the *current net worth* . . . which is $ 61,543,082. This figure was the net worth of [Franklin Corporation] for the 2006 fiscal year, and was substantially the same at the time the jury rendered its verdict and at the time the court conducted its hearing on the Defendant's motion to reduce the punitive damages award . . . .

(Emphasis added.) Pursuant to Mississippi Code Section 11-1-65(3)(a-b), the circuit court ordered that "the punitive damages awarded by the jury . . . are to be reduced to $ 5,000,000 and that the Final Judgment dated

May 31, 2007, be amended to reflect this adjustment." That same day, the circuit court entered an "Order Denying Franklin [Corporation's] Motion for J.N.O.V., or in the Alternative, for New Trial or Remittitur." On July 30, 2007, the "Amended Final Judgment" was entered in favor of the Plaintiffs and against Franklin Corporation in the total amount of $ 7,475,593.59, with post-judgment interest of 8.25 percent. From that ruling, Franklin Corporation filed a "Notice of Appeal," from which the circuit court entered an "Agreed Order for Stay Pending Appeal" **[**36]** as to enforcement of the "Amended Final Judgment."

ISSUES

P28. This Court will consider:

> (1) Whether the Act precludes the Plaintiffs' claims.
>
> (2) Whether the circuit court abused its discretion in admitting the expert testimony of Dr. Kevin Merigian, Dr. Jennifer Majersik, Dr. S.H. Subramony, and Dr. Gaku Ichihara.
>
> (3) Whether the circuit court's granting of certain jury instructions constituted reversible error.
>
> (4) Whether the circuit court abused its discretion in permitting the jury to consider punitive damages.
>
> (5) Whether the punitive damages assessed in the circuit court's "Amended Final Judgment" were erroneous as a matter of law.

ANALYSIS

I. Whether the Act precludes the Plaintiffs' claims.

P29. [HN3] The applicability of the Act, Mississippi Code Section 71-3-1 through 71-3-225, is a question of law. This Court reviews questions of law de novo. *See* ***Miss. Ethics Comm'n v. Grisham,*** 957 So. 2d 997, 1000 (Miss. 2007) (quoting ***32 Pit Bulldogs v. County of Prentiss,*** 808 So. 2d 971, 973 (Miss. 2002)).

P30. Paragraphs three through six *supra* set out the historical background of the Act, along with our pertinent decisions addressing intentional-tort exceptions to the Act. In ***Miller,*** this Court found **[**37]** that **[*231]** [HN4] certain intentional torts are outside the scope of the exclusivity provision contained in Mississippi Code Section 71-3-9. *See* ***Miller,*** 444 So. 2d at 371 ("where an *injury* is *caused by* the *willful act of an employee acting in the course and scope of his employment and in the furtherance of his employer's business,* the [Act] is *not* the *exclusive remedy* available to the injured party") (emphasis added). *See also* ***Royal Oil,*** 500 So. 2d at 442 ("the [Act] does not bar an employee from pursuing a common law remedy against his employer for an injury caused by his employer's wilful and malicious act"). Mississippi law clearly provides that certain intentional torts lie beyond the scope of the Act's exclusivity.

P31. However, in ***Peaster,*** we held that [HN5] "[a] mere willful and malicious act remains insufficient to give rise to the exception under the Act." ***Peaster,*** 642 So. 2d at 348. *See also* ***Blailock,*** 795 So. 2d at 535 ("[r]eckless or grossly negligent conduct is not enough to remove a claim from the exclusivity of the Act."). Before recovery may be had for the specific injuries and/or diseases which the Plaintiffs claim, there must be proof of actual intent to injure by Franklin Corporation. **[**38]** In ***Griffin,*** this Court stated:

> Dunn, *Mississippi Workmen's Compensation,* (3d ed. 1982 & Supp. 1984), notes that [HN6] in order for a willful tort to be outside the exclusivity of the Act, the employee's action must be done "*with an actual intent to injure the employee.* It is not enough to destroy the immunity that the employer's conduct leading to the injury consists of aggravated negligence or even that the conduct goes beyond this to include such elements as knowingly permitting hazardous conditions to exist or willfully failing to furnish a safe place to work or knowingly ordering the employee to perform a dangerous job. [Footnote omitted]." *Id.* at § 22.

Griffin, 533 So. 2d at 464 (emphasis added). After referencing the above-quoted portion of ***Griffin,*** this Court addressed the requisite level of "intent" in ***Peaster.*** *See* ***Peaster,*** 642 So. 2d at 347-49. Issue II therein succinctly placed before the Court the question of whether "this Court should recognize an exception to the exclusive liability provision where the employer has knowingly permitted hazardous conditions to exist which are substantially certain to result in injury or death." ***Id.*** at 348. According to this Court:

> [t]he appellants **[**39]** urge this Court to "*consider enlarging* the scope of the intentional tort exception *to include* those acts which consist of the employer willfully permitting hazardous conditions to exist which are *substantially certain, although perhaps not specifically intended, to result in the injury or death of an employee.*"
>
> . . . .
>
> There is nothing novel about the approach suggested by the appellants of enlarging the scope of the exemption test. We have stated consistently our position on this issue. The legislature has had every opportunity to include into the Act such a liberal exception suggested by the appellants, yet failed to do so. If this Court were to include what the legislature did not, we would violate the "purpose, spirit and philosophy of the [Act]." ***Brown v. Estess,*** 374 So. 2d 241, 242 (Miss. 1979).

Peaster, 642 So. 2d at 348-49 (emphasis added). In conclusion, the ***Peaster*** Court held:

> [HN7] [t]he employer's conduct may have been reckless, negligent, or grossly negligent, but that [is] not enough to remove this case as an "intentional tort" from the exclusivity of the [Act]. This Court has held repeatedly that the employer's action **[*232]** must be done "with an actual intent to injure the employee," **[**40]** and that "an intentional tort is an act of intentional behavior designed to bring about the injury." We do not today choose to expand this Court's interpretation of what constitutes an intentional tort exception. [41]

Id. at 349-50. This view repeatedly has been acknowledged by federal and state courts in Mississippi. *See* ***Bailey v. Lockheed Martin Corp.,*** 432 F. Supp. 2d 665, 671 (S.D. Miss. 2005) (citing ***Peaster*** for the proposition that [HN8] "[t]o be deemed intentional, [the employer's] acts or inaction must be designed to bring about the injury."); ***Thornton v. W.E. Blain & Sons, Inc.,*** 878 So. 2d 1082, 1086 (Miss. Ct. App. 2004) (citing ***Peaster*** for the proposition that this Court "already has declined to create a 'substantial certainty' exception to the exclusivity provision of the Act . . ."). We conclude, once again, that the Act is exclusive absent an actual intent to injure the employee.

41 This is in accord with the standard applied by the majority of states. Of the forty states which recognize an intentional-tort exception to their workers' compensation statutes, only twelve have adopted a broader definition than "actual intent to injure." *See* 6 Larson, *Larson's Workers' Compensation Law* § 103.01 **[**41]** nn.4-6; § 103.04[1]. "Under the most popular formulation, adopted by eight states, an employer is suable in tort if it knows that its conduct causing the injury is 'substantially certain' to cause injury or death." *Id.* at § 103.04[1]. *See also* ***Bazley v. Tortorich,*** 397 So. 2d 475, 480 (La. 1981) (example of application of the "substantially certain" standard).

P32. No party contests that the Plaintiffs' injuries "arose out of and in the course of employment . . . ." Miss. Code Ann. § 71-3-3(b) (Rev. 2000). The circuit court was presented with the issue of whether the Act precluded the Plaintiffs' claims at three distinct stages of this proceeding: Franklin Corporation's "Motion to Dismiss," Franklin Corporation's "Motion for Summary Judgment," and Franklin Corporation's "Motion for J.N.O.V." At each stage, the circuit court rejected Franklin Corporation's contentions otherwise and denied the respective motions. Regarding the "Motion to Dismiss," the circuit court found "that the Plaintiffs have alleged sufficient facts and causes of action, which under the relevant standard of review, satisfy the intentional tort exception to the application of [the Act]." Taking the allegations set **[**42]** forth by the Plaintiffs as true, *see* ***Penn National Gaming, Inc. v. Ratliff,*** 954 So. 2d 427, 430 (Miss. 2007), this Court finds no error in that ruling.

P33. As to the "Motion for Summary Judgment," based upon the collective "pleadings, depositions, answers to interrogatories and admissions on file, together with . . . affidavits," [42] Mississippi Rule of Civil Procedure 56(c), the circuit court concluded that there were "genuine issues of fact as to whether there was intent to injure[,]" with respect to the Plaintiffs' claims of battery and intentional infliction of emotional distress against Franklin Corporation. This Court finds no error in that ruling.

42 Including Clark's testimony from his November 2, 2004, affidavit and November 2, 2005, deposition. *See* footnote 19 *supra.*

P34. Finally, regarding the "Motion for J.N.O.V.," the circuit court found "that during the course of the three week trial . . . there was substantial, credible evidence presented . . . to support the Plaintiffs' causes of action for battery and intentional infliction of emotional distress . . . ." Accordingly, the circuit court concluded that:

> [i]n considering the evidence in the light most favorable to the non-movant, **[**43]** giving that party the benefit of all favorable inferences that may be reasonably **[*233]** drawn from the evidence, and finding that the evidence was of

> such quality and weight that reasonable and fair-minded jurors in the exercise of impartial judgment might have reached different verdicts, the court finds that Defendant Franklin [Corporation's] Motion for J.N.O.V. should be denied.

Given the considerable testimony offered by employees and management personnel of Franklin Corporation, viewed "in the light most favorable to [the Plaintiffs], giving that party the benefit of all favorable inference that may be reasonably drawn from the evidence[,]" ***Spotlite Skating Rink, Inc. v. Barnes,*** 988 So. 2d 364, 368 (Miss. 2008) (citation omitted), this Court affirms the denial of J.N.O.V. given the "substantial evidence [43] to support the verdict." ***Adcock,*** 981 So. 2d at 948.

> 43 [HN9] "Substantial evidence" has been defined as "information of such quality and weight that reasonable and fair-minded jurors in the exercise of impartial judgment might have reached different conclusions." ***Adcock v. Miss. Transp. Comm'n,*** 981 So. 2d 942, 948-49 (Miss. 2008) (citation omitted).

II. Whether the circuit court abused its discretion [44] in admitting the expert testimony of Dr. Kevin Merigian, Dr. Jennifer Majersik, Dr. S.H. Subramony, and Dr. Gaku Ichihara.**

P35. This Court has stated that:

> [HN10] [u]nder Mississippi Rule of Evidence 702, trial courts are charged with being gatekeepers in evaluating the admissibility of expert testimony. [***Irby v. Travis,*** 935 So. 2d 884, 912 (Miss. 2006)]. "We are confident that our learned trial judges can and will properly assume the role as gatekeeper on questions of admissibility of expert testimony." ***Miss. Transp. Comm'n v. McLemore,*** 863 So. 2d 31, 40 (Miss. 2003).

Watts v. Radiator Specialty Co., 990 So. 2d 143, 146 (Miss. 2008). Accordingly, "[t]he trial judge has the sound discretion to admit or refuse expert testimony; an *abuse of discretion standard* means the judge's decision will stand unless the discretion he used is found to be arbitrary and clearly erroneous." ***Troupe v. McAuley,*** 955 So. 2d 848, 856 (Miss. 2007) (quoting ***Poole v. Avara,*** 908 So. 2d 716, 721 (Miss. 2005)) (emphasis added). *See also* ***Bonner v. ISP Tech., Inc.,*** 259 F.3d 924, 932 (8th Cir. 2001) ("[w]e perform only the comparatively narrow analysis of whether the district court's determination that the opinion was sufficiently **[**45]** grounded in 'good science' to assist the jury constituted an abuse of that court's discretion.").

P36. [HN11] Mississippi Rule of Evidence 702 states:

> [i]f scientific, [44] technical, or other specialized knowledge [45] will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable **[*234]** principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Miss. R. Evid. 702. In short, [HN12] the trial judge must "ensure that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands." ***Daubert,*** 509 U.S. at 597. *See also* ***Watts,*** 990 So. 2d at 146 ("[t]his rule makes it necessary for a trial court to apply a two-pronged inquiry when evaluating the admissibility of expert testimony: (1) is the witness qualified, and (2) is the testimony relevant and reliable?"). [HN13] In ***Daubert,*** **[**46]** the United States Supreme Court:

> set out four non-exclusive factors to aid in the determination of whether the methodology is reliable. They are:
>
> > (1) whether the theory or technique has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the method used and the existence and maintenance of standards controlling the technique's operation; and (4) whether the theory or method has been generally accepted by the scientific community.

Curtis v. M&S Petroleum, Inc., 174 F. 3d 661, 668-69 (5th Cir. 1999) (quoting ***Daubert,*** 509 U.S. at 593-94). This approach is "a flexible one. Its overarching subject is the scientific validity -- and thus the evidentiary relevance and reliability -- of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." ***Daubert,*** 509 U.S. at 594-95.

44 [HN14] "'[S]cientific' implies a grounding in the methods and procedures of science." ***Daubert v. Merrell Dow Pharms., Inc.,*** 509 U.S. 579, 590, 113 S. Ct. 2786, 2795, 125 L. Ed. 2d 469, 481 (1993).

45 [HN15] "Knowledge" applies to "'any body of known **[**47]** facts or to any body of ideas inferred from such facts or accepted as truth on good grounds.' Webster's Third New International Dictionary 1252 (1986). Of course, it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty." ***Daubert,*** 509 U.S. at 590. Furthermore, "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." ***Id.***

P37. Dr. S.H. Subramony, Dr. Kevin Merigian, Dr. Gaku Ichihara, and Dr. Jennifer Majersik were among the Plaintiffs' designated experts. The deposition testimony of Dr. Subramony, a board-certified neurologist, was that after reviewing the Plaintiffs' medical records, along with pertinent literature on 1-BP, [46] "my interpretation of these four patients is that they had varying degrees of this same problem[,]" namely, residual neurological deficits from exposure to 1-BP. In offering this opinion, Dr. Subramony conceded that he was unaware of the exact concentration of 1-BP to which the Plaintiffs had been exposed. Nonetheless, Dr. Subramony averred that his conclusions and opinions "are supported by the overwhelming facts and the extensive data available on **[**48]** the effects of 1-BP on animals as well as humans, and were reached by using sound methods that are widely accepted in the medical and scientific community."

46 This literature included, most notably, the abstract to a case report by Dr. Majersik indicating that "[1-BP] is reportedly [harmful to humans at] about 25 [ppm]." Dr. Majersik's case report, co-authored by E. Martin Caravati, M.D., and John D. Steffens, M.D., was subsequently published as "Severe neurotoxicity associated with exposure to the solvent 1-bromopropane (n--propyl bromide)" in *Clinical Toxicology* 45 at 270-76 (2007).

P38. The deposition testimony of Dr. Merigian, the treating physician for the Plaintiffs, was that their injuries were caused by exposure to 1-BP. [47] In rendering this opinion, Dr. Merigian admitted that he was unaware of the exact concentration of 1-BP to which the Plaintiffs were exposed or the precise exposure level at which 1-BP becomes harmful to humans. **[*235]** Nonetheless, Dr. Merigian based his conclusion upon his examination of the Plaintiffs, an internet search regarding 1-BP, [48] the "common finding" in tests run by other physicians on the Plaintiffs, his review of the Soft Seam MSDS, and the fact that **[**49]** "[t]hey all worked within a spray area that had been modified [in September 2003] and they were using a type of glue that is a known neurotoxin. And as [Franklin Corporation] manipulated the environment to prevent the glue from going onto other individuals within the factory itself, the symptoms and signs arose." As Dr. Merigian stated, "[t]he bottom line is it all fits together." He added that when he spoke with Shempert by phone, "[Shempert] . . . commented that the glue caused these issues but . . . he would not be responsible because he was ignorant to the fact that the glue would cause the problem."

47 This comports with the deposition testimony of Franklin Corporation's expert, Dr. George Wilkerson, that exposure to 1-BP was sufficient to, and did, cause the neurologic injuries suffered by Plaintiffs Tedford and Haire.

48 According to Dr. Merigian, "[t]here was a physician who had written some case reports or a case report about some exposures to [1-BP], and then there was a lot of animal data on rats with [1-BP]." Dr. Merigian later identified this case report as that authored by Dr. Majersik. *See* footnote 46 *supra.*

P39. The deposition testimony of Dr. Ichihara, an occupational toxicologist **[**50]** and a leading expert on 1-BP toxicity, [49] was that "we . . . believe if exposure level is higher than some levels, . . . such overexposure to [1-BP] can cause neurological damage in humans even [if] we don't know the . . . very precise relationship of the dose response." He based this opinion upon case reports which he had both authored and reviewed. [50] While conceding that he had not examined the Plaintiffs and was not aware of the exact concentration of 1-BP to which they were exposed, Dr. Ichihara offered his opinion to a reasonable degree of medical and scientific probability that the Plaintiffs' symptoms and health problems were due to exposure to 1-BP. [51]

49 According to the deposition testimony of Dr. Caravati, "it would be difficult to find anyone anywhere who would be more qualified to render" an expert opinion on the toxicity of 1-BP to humans than Dr. Ichihara. Even Franklin Corporation's expert, Dr. Robert Cox, stated that Dr. Ichihara "is one of the leading researchers that published on [1-BP]."

50 These include the case report entitled "Encephalomyeloradiculoneuropathy following exposure to an industrial solvent" by Gary Schlar in *Clinical Neurology and Neurosurgery* 101 at **[**51]** 199-202 (1999); Dr. Ichihara's own case report entitled "Neurological Disorders in Three Workers Exposed to 1-Bromopropane" in *Journal of Occupational Health* 44 at 1-7 (2002); and Dr. Majersik's case report. *See* footnote 46 *supra.*

51 He added that he had never seen a workplace using 1-BP for five years without any ventilation system. Dr. Caravati found the opinions of Dr. Ichihara to be "based upon sufficient data and facts[,]" the byproduct "of reliable principles and methods that are acceptable and utilized in the community of expert toxicologists[,]" and the result of "correctly appl[ying] the pertinent principles and methods to the relevant facts and data . . . ."

P40. The deposition testimony of Dr. Majersik, a board-certified neurologist, was that few studies have been done on the effect of 1-BP on humans. Based upon her case report, "[w]e know that my patients had neurologic damage at . . . [108 ppm]. . . . We don't know how long it takes, . . . how many weeks, months, days, hours of exposure it takes. All we have are discrete points in time to say somebody had this problem . . . ." [52]

52 As Dr. Majersik stated, the underlying problem in determining the precise lower level of 1-BP **[**52]** exposure which causes neurologic damage in humans is that a physician cannot ethically "put a bunch of people in a room . . . expose them to glue and see what happens as a case series."

P41. Franklin Corporation subsequently filed or joined motions *in limine* to **[*236]** conduct a ***Daubert*** hearing, seeking to exclude the expert opinion testimony of Dr. Subramony, Dr. Merigian, [53] Dr. Ichihara, and Dr. Majersik. The Plaintiffs responded that "[a]t the core of the Defendants' motions, the Defendants invite the [c]ourt to ignore the sworn testimony of experts in their respective fields, and they seek to have the [c]ourt journey down the road of 'microanalysis' of each expert's opinions." Following hearing, the circuit court denied Franklin Corporation's ***Daubert*** motions as to each physician. Regarding Dr. Ichihara, the circuit judge stated "that is the one that is not hard for me . . . . [I]t's logical to[ward] that the jury understands that this stuff is dangerous and, . . . so, yes. I think it has a value. I think that this testimony is . . . going to assist the jury, finder of fact." As to Dr. Subramony, Dr. Merigian, and Dr. Majersik:

> the [c]ourt is going to make a *provisional ruling* here today **[**53]** so that the parties can go forward and that will be the [c]ourt will accept them as tendered in their fields of expertise and that they meet the ***Daubert*** criteria for expert testimony assisting the trier of fact. Specifically, including that *they are qualified in their fields.* That *their opinions are helpful to the jury* and *the opinions that they render are relevant* and that *their opinions are based upon reliable methodologies. I think this is a field with limited reliable methodology* . . . . I reserve the right to change my mind but that is the ruling here today and that is the one I would ask that you rely on in proceeding hence forth.

(Emphasis added.)

53 Franklin Corporation's motions with respect to Dr. Subramony and Dr. Merigian specifically stated that their opinions on causation were "offered despite [their] inability to state: (1) what level of exposure to [1-BP] is needed to cause neurologic injuries in humans; and (2) what levels of exposure the Plaintiffs experienced." The affidavit and testimony of Dr. Robert Cox, a board-certified physician in medical toxicology and emergency medicine, was offered by Franklin Corporation to support this criticism. In response, the Plaintiffs **[**54]** offered the deposition testimony of Dr. Caravati, whom Dr. Cox acknowledged to be an expert in the field of toxicology, providing "[i]t is my opinion that Dr. Merigian's opinions that he initially formulated as a treating physician with a toxicological background were based upon sufficient data and facts to enable Dr. Merigian to render his opinions."

P42. At trial, each physician was tendered and accepted in his or her respective field of expertise without objection. [54] Based upon her education and expertise, her review of the Plaintiffs' medical records, her research on the subject of 1-BP toxicity, and her case report, [55] Dr. Majersik opined "that the levels at which these [P]laintiffs were exposed was sufficient to cause the neurologic damage as I read about the damage from the physicians' reports." While admitting that the lower level of harmful exposure to 1-BP has not yet been discovered, she stated that "it seems that the exposure levels and the conditions the patients had is adequate for my expert opinion." Dr. Subramony testified that:

> I concluded that their history of exposure was causative because they all had **[*237]** a very similar story. They all had similar findings on neurological **[**55]** examination, and they all were getting better after the exposure was removed, and none of the laboratory studies and brain scan studies . . . done by other people had revealed any other cause for this.

Although Dr. Subramony conceded that he did not know the Plaintiffs' level of exposure to 1-BP, his opinion, to a reasonable degree of medical probability, was that their exposure level was injury-causing, based upon "temporal association" and research reflecting that exposure to 1-BP can cause neurologic injury. At trial, Dr. Merigian acknowledged that he did not know the lower level of exposure to 1-BP that causes neurologic injury to humans, but he reiterated his opinion, to a reasonable degree of medical probability, that 1-BP caused the Plaintiffs' injuries. [56]

> 54 Dr. Subramony was tendered and accepted as an expert in the field of neurology. Dr. Merigian was tendered and accepted as an expert "in the field of general practice and as a treating physician of the [P]laintiffs in this case." Dr. Majersik was tendered and accepted as an expert "in the field of neurology and clinical findings associated with the [1-BP] toxicity and neurological injury."
>
> 55 According to Majersik, based upon **[**56]** the OSHA report, the Plaintiffs experienced "about twice the exposure level" of Majersik's case-report patients. Moreover, the patients in her case report exhibited "very similar" symptoms to the Plaintiffs.
>
> 56 According to Dr. Merigian, the results of the air testing at Franklin Corporation "helped solidify" his opinions.

P43. On appeal, Franklin Corporation argues that "[e]ach of the Plaintiffs' four experts exhibits a fatal flaw. None knew of the [1-BP] exposure level at which injury occurs in humans . . . . None knew of the exposure experienced by the particular Plaintiffs." As such, Franklin Corporation contends that their "testimony does not meet the requirements of admissibility of expert testimony under M.R.E. 702."

P44. At trial, Franklin Corporation did not object to the tender of Dr. Subramony, Dr. Merigian, Dr. Ichihara, and Dr. Majersik as experts, or to their actual testimony. Therefore, this Court will limit its analysis to the circuit court's denial of Franklin Corporation's ***Daubert*** motions as to each physician. [HN16] Only if the circuit judge abused his discretion in so ruling, acting in an "arbitrary and clearly erroneous" manner, will this Court find error. *See* ***Troupe,*** 955 So. 2d at 856.

P45. **[**57]** The neurological impact of 1-BP on humans is a relatively new field of study. As the circuit judge stated, "this is a field with limited reliable methodology . . . ." Furthermore, as Dr. Majersik noted, determining the exact lower level of 1-BP exposure which causes neurologic injury in humans is challenging, given appropriate, ethical constraints. At best, nondefinitive determinations have been rendered via relevant case reports, [57] MSDSs, [58] and organizational recommendations. This Court finds such sources to be sufficient. "[I]t would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty." ***Daubert,*** 509 U.S. at 590. "[T]he first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victims' condition and the toxic substance, has not yet been completed." ***Bonner,*** 259 F. 3d at 928 (quoting ***Turner v. Iowa Fire Equip. Co.,*** 229 F. 3d 1202, 1208-09 (8th Cir. 2000)). Similarly, this Court finds that the absence of data on the exact exposure level at which humans suffer neurologic injury ought not preclude the Plaintiffs' **[**58]** experts from testifying, when combined with Franklin Corporation's **[*238]** stipulation that 1-BP is a neurotoxin which can cause neurologic injury to humans and the testimony of its expert, Dr. George Wilkerson, that exposure to 1-BP caused the neurologic injuries suffered by Plaintiffs Tedford and Haire (despite not knowing the exact level at which 1-BP causes injury in humans).

> 57 [HN17] "While case-study review is certainly an accepted methodology, trial courts still must be certain that the content of those case studies is *relevant* to the facts at hand." ***Watts,*** 990 So. 2d at 146 (emphasis added).
>
> 58 As the expert in ***Curtis*** noted, "the MSDS is a valid and accurate portrayal of the hazards . . . because [MSDSs] are prepared to have all of the information regarding health and environmental hazards, and because the manufacturer is required to research the best, peer-reviewed scientific literature to form these [MSDSs]." ***Curtis,*** 174 F. 3d at 669.

P46. The collective case reports, MSDSs, and organizational recommendations, paired with the direct and circumstantial evidence in the case *sub judice,* support a causal connection between the Plaintiffs' exposure to 1-BP and their injuries. *See* ***Curtis,*** 174 F. 3d at 670 **[**59]** ("[i]n the present case, both scientific literature and strong circumstantial evidence support the causal connection."). " [HN18] Under some circumstances, a strong temporal connection is powerful evidence of causation." ***Bonner,*** 259 F. 3d at 931. Causal connection is further validated by the results of the air testing performed by Housman, Parker, and OSHA. These tests established that the Plaintiffs were "exposed to a quantity of the toxin that 'exceeded safe levels.'" ***Id.*** (quoting ***Bednar v. Bassett Furniture Mfg. Co.,*** 147 F. 3d 737, 740 (8th Cir. 1998)). As such, this Court finds that there was sufficient "'evidence from which a reasonable person could conclude' that [the Plaintiffs'] exposure probably caused [their] injuries." ***Id.*** at 928. Accordingly, we find no abuse of discretion by the circuit judge in admitting the expert testimony of Dr. Subramony, Dr. Merigian, Dr. Ichihara, and Dr. Majersik, as their qualifications were not legitimately questioned, and their testimony was sufficiently relevant and reliable. *See* ***Watts,*** 990 So. 2d at 146.

III. Whether the circuit court's granting of certain jury instructions constituted reversible error.

P47. On appeal, Franklin Corporation argues that **[**60]** Instructions P-2, P-3, and P-4A, considered as a whole, incorrectly state the law and exist in "substantial conflict" with Instruction D1-2, thereby requiring reversal. Instruction D1-2 states:

> [t]he Court instructs the Jury that in order to recover on their claims against Defendant Franklin Corporation, the Plaintiffs have the burden of proving by a preponderance of the credible evidence that Franklin knowingly exposed the Plaintiffs to unreasonably dangerous levels of the industrial solvent which contained [1-BP] with an actual intent to cause them injury. It is not enough for the Plaintiffs to prove that Defendant Franklin negligently or even knowingly permitted hazardous conditions to exist, or that it negligently or even willfully failed to furnish the Plaintiffs with a safe place to work, or that it knowingly ordered the Plaintiffs to perform a dangerous job. If, and only if, you find from a preponderance of the credible evidence that Defendant Franklin engaged in conduct designed to cause the injuries for which the Plaintiffs claim damages, may you find for the Plaintiffs. If you find by a preponderance of the credible evidence that the Plaintiffs have failed to prove that Defendant **[**61]** Franklin knowingly exposed them to unreasonably dangerous levels of the industrial solvent which contained [1-BP] with an actual intent to cause them injury, then it is your sworn duty to return a verdict for Defendant Franklin Corporation on each of the Plaintiffs' claims.

Instruction P-2 provides, in part, that:

> [i]n order to establish that an intentional tort was committed by Defendant, Franklin Corporation, Plaintiffs must prove that, more likely than not, Defendant, Franklin Corporation either desired to cause the consequences of its acts, or believed that the consequences were substantially certain to result from **[*239]** it. Said another way, if Franklin Corp. knew that the consequences were certain, or substantially certain, to result from its acts, and still goes ahead, Franklin Corp. is treated by the law as if it had in fact desired to produce the result.

Instruction P-3 states:

> [t]he Court instructs you that with regard to the intentional torts alleged by Plaintiffs against Defendant Franklin Corp., battery and intentional infliction of emotional distress, intent may be inferred from the circumstances of the case. Intent is an emotional operation of the mind, and is usually shown by **[**62]** acts and declarations of the defendant coupled with facts and circumstances surrounding him at the time. A defendant's intention is manifested largely by the things he does.

Instruction P-4A regarding battery provides, in part, that:

> if you find by a preponderance of the evidence that Franklin Corp. intended that the Plaintiffs used the glue containing [1-BP], and that Defendant Franklin Corporation knew that Plaintiffs would inhale the vapors/fumes and that such inhalation was known to Franklin Corporation to be causing physical harm to the Plaintiffs, and/or substantially certain to cause physical harm to the Plaintiffs, and that such harmful or offensive contact with the glue vapors/fumes occurred, and that such harmful or offensive contact caused or contributed to cause injury to the Plaintiffs, then it is your duty to return a verdict in favor of the Plaintiffs and against Franklin Corp.

P48. [HN19] In reviewing the grant or denial of jury instructions, this Court has stated that:

> we are required to review all of the instructions as a whole. ***Richardson v. Norfolk & Southern Ry.,*** 923 So. 2d 1002, 1010 (Miss. 2006). No instruction should be reviewed in isolation. ***Burr v. Miss. Baptist Medical Ctr.,*** 909 So. 2d 721, 726 (Miss. 2005). **[**63]** When analyzing the grant or refusal of a jury instruction, two questions should be asked: Does the instruction contain a correct statement of law and is the instruction warranted by the evidence? ***Hill v. Dunaway,*** 487 So. 2d 807, 809 (Miss. 1986). Defects in specific instructions will not mandate reversal when all of the instructions, taken as a whole fairly -- although not perfectly -- announce the applicable primary rules of law. ***Burton v. Barnett,*** 615 So. 2d

580, 583 (Miss. 1993). The above standards notwithstanding, this Court will not hesitate to reverse if the instructions, when analyzed in the aggregate, do not fairly and adequately instruct the jury. ***Richardson,*** 923 So. 2d at 1011.

Beverly Enters. v. Reed, 961 So. 2d 40, 43 (Miss. 2007).

P49. We find that the conflict between Instruction D1-2 and Instructions P-2 and P-4A does not rise to the level of reversible error when read in conjunction with the other instructions. Without doubt, the references to "substantially certain" in Instructions P-2 and P-4 were erroneous. [HN20] The Act is exclusive absent an actual intent to injure the employee. *See* P 31 *supra.* However, that phrase was not presented to the jury in isolation, for **[**64]** they also received Instructions D1-2, P-3, and the special interrogatory (Instruction P-10a).

P50. Franklin Corporation's Instruction D1-2 includes the appropriate standard. Had that standard not been furnished to the jury, the outcome which we reach likely would be different. However, as this Court stated in ***Lamar Hardwood Co. v. Case,*** 143 Miss. 277, 107 So. 868 (1926), "[w]e think the law as given to the **[*240]** defendant upon this proposition gives him the benefit of all that he was entitled to have upon the question." ***Id.*** at 289.

P51. Instruction P-2, read in its entirety, is a correct statement of the law but for the reference to "substantially certain." Instruction P-3 is a proper statement of law without flaw. [59] Finally, a special interrogatory (Instruction P-10a) confirmed that the jury specifically found for each individual Plaintiff on his or her battery and intentional-infliction-of-emotional-distress claims against Franklin Corporation, while exonerating Mid-South.

59 Regarding Instruction P-3, Franklin Corporation objected to the language that "intent may be inferred from the circumstances of the case." The circuit judge overruled that objection, deeming the above-quoted language **[**65]** to be a correct statement of the law. This Court agrees. *See* ***Miss. Bd. of Nursing v. Wilson,*** 624 So. 2d 485, 494 (Miss. 1993) (citing ***Hollingsworth v. State,*** 392 So. 2d 515 (Miss. 1981)) ([HN21] "[i]t is well settled that intent may be shown by circumstances.").

P52. [HN22] The law requires all instructions to be read together. *See* ***id.*** at 290 ("the instructions must be taken together and be construed as a whole, one as modifying, explaining or qualifying another; and, if the instructions taken as a whole correctly announce the law applicable to the case, we will not reverse the judgment because of an imperfect single instruction."). "Where it may be fairly charged that one or more instructions may have been confusingly worded, we should not reverse if other instructions clear up the confusing points." ***Payne v. Rain Forest Nurseries, Inc.,*** 540 So. 2d 35, 40 (Miss. 1989). "Defects in specific instructions do not require reversal 'where all instructions taken as a whole fairly -- although not perfectly -- announce the applicable primary rules of law.'" ***Burton,*** 615 So. 2d at 583 (quoting ***Payne,*** 540 So. 2d at 40).

P53. We also have held that [HN23] a conflict between instructions does not justify reversal, given **[**66]** that the evidence overwhelmingly supported the Plaintiffs' claims and does not result in a miscarriage of justice. *See* ***Smith v. Mack Trucks, Inc.,*** 819 So. 2d 1258, 1261 (Miss. 2002); ***Smith v. Jones,*** 335 So. 2d 896, 897 (Miss. 1976). In short, "[t]he conflict in the evidence made the jury the judges of what the truth was with reference thereto, and we are unable to say that the jury reached the wrong result." ***Case,*** 143 Miss. at 289.

IV. Whether the circuit court abused its discretion in permitting the jury to consider punitive damages.

P54. " [HN24] [T]he primary purpose of punitive damages is to punish the wrongdoer and deter similar misconduct in the future by the defendant and others . . . ." Miss. Code Ann. § 11-1-65(1)(e) (Rev. 2002). "Punitive damages may not be awarded if the claimant does not prove by *clear and convincing evidence* that the defendant against whom punitive damages are sought acted with *actual malice, gross negligence which evidences a willful, wanton or reckless disregard for the safety of others, or committed actual fraud.*" Miss. Code Ann. § 11-1-65(1)(a) (Rev. 2002) (emphasis added). *See also* ***Paracelsus Health Care Corp. v. Willard,*** 754 So. 2d 437, 442 (Miss. 1999) (citation **[**67]** omitted) ("[p]unitive damages are only appropriate in the most egregious cases so as to discourage similar conduct and should only be awarded in cases where the actions are extreme."). "[T]he trial court is the gatekeeper for the issue of whether punitive damages, in cases involving both intentional **[*241]** and non-intentional torts, should be submitted and considered by a jury." ***Doe v. The Salvation Army,*** 835 So. 2d 76, 79 (Miss. 2003). " [HN25] An *abuse of discretion* standard is implemented when this Court reviews the trial court's decision of whether a case warrants punitive damages to be sent to the

trier of fact." ***Id.*** at 81 (citing ***Hurst v. Sw. Miss. Legal Servs. Corp.,*** 708 So. 2d 1347, 1351 (Miss. 1998)) (emphasis added).

P55. According to the circuit judge:

> [t]here's no question that the matters submitted *in this [c]ourt's opinion,* submitted to the jury as to *the burden of proof required in this case for the showing required to avoid . . . the exclusive remedy of Workers' Comp is, in fact, higher than the standard called for in the statute for punitive damages.* There's no good resolution of that, but we just have to act the best we can based on the information we do have.
>
> The [c]ourt finds that **[**68]** in consideration of all the proof that has . . . gone into evidence over the last three weeks that . . . the jury . . . did make an award of compensatory damages; and it was more than a nominal amount of money; and *the [c]ourt believes, based on the proof offered here at this hearing, that it's absolutely appropriate that the jury consider the question of punitive damages* . . . .

(Emphasis added.) In short, the circuit judge found there was sufficient evidence to meet the "clear and convincing" standard required for punitive damages. We find that the circuit court did not abuse its discretion in permitting the jury to consider punitive damages.

V. Whether the punitive damages assessed in the circuit court's "Amended Final Judgment" were erroneous as a matter of law.

P56. [HN26] The proper assessment of punitive damages under Mississippi Code Section 11-1-65(3) is a question of law, to be reviewed by this Court de novo. *See* ***Grisham,*** 957 So. 2d at 1000.

P57. For all actions filed before September 1, 2004, [60] [HN27] Mississippi Code Section 11-1-65(3) provided, in pertinent part, that:

> (a) In any civil action where an entitlement to punitive damages shall have been established under applicable laws, no **[**69]** award of punitive damages shall exceed the following: . . .
>
> > (v) Five Million Dollars ($ 5,000,000.00) [61] for a defendant with a net worth of more than Fifty Million Dollars ($ 50,000,000.00) but not more than One Hundred Million Dollars ($ 100,000,000.00); or
> >
> > (vi) Four percent (4%) [62] of the defendant's net worth for a defendant with a net worth of Fifty Million Dollars ($ 50,000,000.00) or less.
>
> (b) For the purposes of determining the defendant's net worth in paragraph (a), the amount of the net worth shall be determined in accordance with Generally Accepted Accounting Principles.

Miss. Code Ann. § 11-1-65(3) (Rev. 2002).

60 The Complaint in the case *sub judice* was filed on August 16, 2004.

61 On and after September 1, 2004, this figure became $ 2,500,000. Miss. Code Ann. § 11-1-65(3)(a)(v) (Rev. 2002).

62 On and after September 1, 2004, this figure became two percent (2%). Miss. Code Ann. § 11-1-65(3)(a)(vi) (Rev. 2002).

P58. Jeffrey Cox, the chief financial officer and general counsel for Franklin Corporation, testified that the net worth of **[*242]** Franklin Corporation was $ 45,905,326 in 2003 and $ 37,810,166 in 2004. According to Cox, as of December 31, 2006, the net worth of Franklin Corporation **[**70]** was "approximately [$ 61,500,000]." He did not believe that figure was substantially different at the time of trial, and further testified that "Generally Accepted Accounting Principles" were applied in determining that figure. In the "Order Granting Motion to Reconsider Punitive Damages, to Alter or Amend Final Judgment, for Relief from Final Judgment, or for Other Relief," the circuit court stated:

> the language of Miss. Code Ann. Section 11-1-65 which relates to the imposition of the legislative caps to a punitive damage award provides that the net worth of the defendant "shall be determined" in accordance with Generally Accepted Accounting Principles, and that *such language implies that the current net worth of the defendant is to be considered.* Further, other portions of the statute refer to the net worth of the defendant as a factor to be considered in an effort to determine the defendant's financial ability to pay the award, and likewise implies that the current net worth of the de-

> fendant is to be utilized . . . . Further, there is no language in the statute which provides that the past net worth of the defendant is to be utilized, and without such distinguishing language, *this* **[**71]** *court must apply the common meaning of the term "net worth," as well as the common interpretation as afforded by a reading of the statute as a whole.* [63]

(Emphasis added.) Applying "the current net worth" of Franklin Corporation, the circuit court reduced the punitive damages owed to $ 5,000,000 pursuant to Mississippi Code Section 11-1-65(3)(a)(v).

> 63 The circuit judge added that this application furthers the policy behind the imposition of punitive damages, "result[ing] in financial punishment to the defendant in an amount that makes the defendant earnestly consider its actions in the future."

P59. This Court previously has considered the net worth of a defendant *at the time of trial. See* ***Willard,*** 754 So. 2d at 445. *See also* ***Cash v. Beltmann North American Co.,*** 900 F.2d 109, 111 n.3 (7th Cir. 1990) ("[f]inancial data prepared for income tax purposes and four years old at the time of trial provides weak evidence of Beltmann's true net worth."). Furthermore, "the primary purpose of punitive damages is to punish the wrongdoer and deter similar misconduct in the future by the defendant . . . ." Miss. Code Ann. § 11-1-65(1)(e) (Rev. 2002). As such, the circuit court's application of the pre-September **[**72]** 2004 version of the statute and Franklin Corporation's net worth *at the time of judgment* was proper.

CONCLUSION

P60. Accordingly, this Court affirms the "Amended Final Judgment" of the Circuit Court of Calhoun County.

P61. **AFFIRMED.**

WALLER, C.J., CARLSON AND GRAVES, P.JJ., DICKINSON, LAMAR, KITCHENS, CHANDLER AND PIERCE, JJ., CONCUR. GRAVES, P.J., SPECIALLY CONCURS WITH SEPARATE WRITTEN OPINION. DICKINSON, J., SPECIALLY CONCURS WITH SEPARATE WRITTEN OPINION JOINED BY WALLER, C.J., CARLSON, P.J., RANDOLPH, LAMAR, AND PIERCE, JJ.

CONCUR BY: GRAVES; DICKINSON

CONCUR

GRAVES, PRESIDING JUSTICE, SPECIALLY CONCURRING:

P62. I fully concur with the majority that the judgment of the trial court must be affirmed. However, I write separately **[*243]** to address the use of the phrase "substantially certain" in the jury instructions.

P63. The majority finds that the references to "substantially certain" in Instructions P-2 and P-4 were in error. [64] I disagree with the majority inasmuch as the instructions contain a correct statement of the law. The majority cites ***Peaster v. David New Drilling Co.,*** 642 So. 2d 344 (Miss. 1994), ***Blailock v. O'Bannon,*** 795 So. 2d 533, at 535 (Miss. 2001), and ***Griffin v. Futorian Corp.,*** 533 So. 2d 461 (Miss. 1988), **[**73]** in attempting to define "actual intent." However, these cases neither stand for nor support the proposition suggested by the majority. In ***Peaster,*** this Court found:

> In the complaint it was alleged that David New Drilling "willfully" disregarded its duties to Jimmy Wilcoxson, "intentionally" failed to repair the brakes on the tractors and trailers, acted with "gross and reckless disregard for the rights and safety of the public in general and particularly of Plaintiffs' decedent" ***and with "knowledge of substantial certainty of injury." Despite these allegations, the overwhelming language and facts point to negligence, including gross negligence.***

Peaster, 642 So. 2d at 346 (emphasis added).

> 64 Even so, the majority ultimately finds any error to be harmless.

P64. Clearly, the upshot of the ***Peaster*** decision was that this Court found that Plaintiff Peaster had failed to prove the allegations, which included "knowledge of substantial certainty of injury," and thus had failed to

establish "actual intent." There was no discussion or finding in ***Peaster*** to support the proposition that the "actual intent" exception cannot and does not include "knowledge of substantial certainty of injury." Moreover, **[**74]** the majority's discussion of ***Griffin*** likewise fails to support this proposition. In ***Peaster,*** this Court quoted the following from ***Griffin:***

> Dunn, Mississippi Workmen's Compensation, (3d ed. 1982 & Supp. 1984), notes that in order for a willful tort to be outside the exclusivity of the Act, the employee's [sic] action must be done "with an actual intent to injure the employee. It is not enough to destroy the immunity that the employer's conduct leading to the injury consists of aggravated negligence or even that the conduct goes beyond this to include such elements as knowingly permitting hazardous conditions to exist or willfully failing to furnish a safe place to work or knowingly ordering the employee to perform a dangerous job."

Peaster, 642 So. 2d at 347 (quoting ***Griffin,*** 533 So. 2d at 464). This Court further said:

> Griffin [sic] absolutely bars an intentional tort claim even where the probability of gross negligence exists. Thus, in the case sub judice, even if the appellants could prove that David New Drilling was guilty of gross negligence, such a finding would remain insufficient to create an intentional tort and accordingly remove the appellants' claim from under the Workmens' **[**75]** [sic] Compensation Act. A mere willful and malicious act remains insufficient to give rise to the exception under the Act.

Id. at 348.

P65. Notably, in discussing ***Peaster's*** assertion that this Court recognize a substantially-certain exception and apply the Restatement definition of intent, this Court found that:

> ***What the appellants propose is not particularly new or inconsistent with the previous decisions of this Court. As noted, this Court has previously*** **[*244]** ***considered the Restatement's interpretation of intent. The problem is that the allegations of the complaint and all evidence before the lower court fall far short of the substantial certainty which is required.***

Id. at 349 (emphasis added).

P66. Further, Black's Law Dictionary defines "intentionally" as follows, in relevant part: "To do something purposely, and not accidentally . . . . Person acts 'intentionally' if he desires to cause consequences of his act or he ***believes consequences are substantially certain to result*** . . . ." Black's Law Dictionary 810 (6th ed. 1990) (citation omitted) (emphasis added). Black's defines "actual" as: "Real; ***substantial;*** existing presently in fact; having a valid objective existence as opposed to that **[**76]** which is merely theoretical or possible . . . ." Black's Law Dictionary at 34 (emphasis added). Black's also notes the following in the definition of "intent": "The word 'intent' is used throughout the Restatement of Torts, 2nd, to denote that the actor desires to cause consequences of his act, or that he believes that the consequences are ***substantially certain*** to result from it . . . ." Black's Law Dictionary at 810 (emphasis added).

P67. Therefore, I would find that there is no error in including substantially-certain language in the jury instructions along with language of actual intent.

DICKINSON, JUSTICE, SPECIALLY CONCURRING:

P68. Although I concur with the majority, I write separately to address two points.

I.

P69. The majority correctly holds that -- absent an actual intent to injure the employee -- the "exclusive-remedy" provisions of the Mississippi Workers Compensation Act (the "Act") apply to injuries inflicted by employers upon employees. The vast majority of states, including Mississippi, hold this view, even where the employer's conduct is substantially certain to result in injury. 6 Arthur Larson, Larson's Workers' Compensation Law § 103.03 (2008).

> [T]he common-law liability **[**77]** of the employer cannot under the almost unanimous rule, be stretched to include accidental injuries caused by the gross, wanton, wilful, deliberate, intentional, reckless, culpable, or malicious negligence, breach of statute, or other misconduct of the employer short of a conscious and deliberate intent directed to the purpose of inflicting an injury.

Id. (footnotes omitted). Although thirty-eight jurisdictions (including Mississippi) "follow the rule that actual intent to injure is necessary to come outside of the exclusivity provision," twelve states disagree. Thus, "in recent years there has been a trend toward permitting common law suits when the injury is the result of actions the employer knew were 'substantially certain' to cause injury. About a dozen states [65] now follow this or a similar rule." Larson's § 103.03 n.1. However, our precedent holds that:

> [i]t is not enough to destroy [Workers Compensation] immunity that the employer's conduct leading to the injury consists of . . . knowingly permitting hazardous conditions to exist or willfully failing to furnish a safe place to work or knowingly ordering the employee to perform a dangerous job . . . . This Court has held repeatedly **[**78]** that the employer's action must be done with an actual intent **[*245]** to injure the employee, and that "an intentional tort is an act of intentional behavior designed to bring about the injury."

Peaster v. David New Drilling Co., 642 So. 2d 344 (Miss. 1994) (internal citations omitted).

65 Connecticut, Louisiana, New Jersey, North Carolina, Ohio, Oklahoma, South Dakota, Texas, California, Michigan, Washington, and West Virginia.

P70. In 1988, this Court reviewed an injured worker's argument that the Court should "recognize that the injuries sustained by him constitute a new tort outside the exclusivity rule of the [Act]." ***Griffin v. Futorian Corp.,*** 533 So. 2d 461, 463 (Miss. 1988). Speaking for a unanimous Court, Chief Justice Roy Noble Lee stated that "[s]ome states have amended their worker's compensation acts to make exceptions to the exclusive remedy. Mississippi's act has not been amended in that respect since its passage." ***Id.*** at 463. Recognizing (as the majority does today) that an actual intent and design to injure is necessary, the ***Griffin*** Court cited with approval the following authority:

> [I]n order for a willful tort to be outside the exclusivity of the Act, the [employer's] action must **[**79]** be done "with an actual intent to injure the employee. It is not enough to destroy the immunity that the employer's conduct leading to the injury consists of aggravated negligence or even that the conduct goes beyond this to include such elements as knowingly permitting hazardous conditions to exist or willfully failing to furnish a safe place to work or knowingly ordering the employee to perform a dangerous job."

Griffin v. Futorian Corp., 533 So. 2d at 464 (citing Dunn, Mississippi Workmen's Compensation (3d ed. 1982 & Supp. 1984)) (emphasis added). [66] It is of some significance that -- since ***Griffin*** was handed down some twenty years ago -- the Legislature has taken no action to address or contradict its holding.

66 The above quoted language from *Dunn* is correct. However, the ***Griffin*** Court mistakenly indicated that the "employee's" act, rather than the employer's act, must be done with actual intent to injure. Thus, the ***Griffin*** Court included a typographical error. We therefore now make the correction.

P71. Thus, absent the employer's deliberate intent and design to injure the employee, the law in Mississippi -- as it currently exists -- does not allow an injured employee to escape the **[**80]** exclusive-remedy provisions of the Act. The law on this point is so clear that discussion of the contrary view is unnecessary. And upon this point, I fully concur with the majority.

II.

P72. Another point I believe important concerns the procedure for presenting to the trial court an assertion that the Act provides a plaintiff's exclusive remedy. As a matter of procedure, in order to preserve the issue for appeal, a defendant should raise the matter in the first instance as an affirmative defense or (as in the case before us today) in a motion to dismiss. The converse is also true, that is, the plaintiff has no duty to raise or argue the issue.

P73. Black's Law Dictionary defines an affirmative defense as "[a] defendant's assertion of facts and arguments that, if true, will defeat the plaintiff's . . . claim, even if all the allegations in the complaint are true." Black's Law Dictionary 356 (8th ed. 2005). Franklin's position is that -- even though everything the plaintiffs say in this lawsuit may be true -- it is nonetheless entitled to dismissal from this civil suit, because the Act provides the plaintiffs' exclusive remedy.

P74. As stated, in the case before us, Franklin raised the **[**81]** question by motion to dismiss, and the trial judge denied the **[*246]** motion, finding that the issue involved a question of fact. Thus, Franklin properly preserved the issue for appeal.

P75. Furthermore, a defendant seeking to escape tort liability via an affirmative defense has the additional duty to seek a jury instruction for that affirmative defense which places the burden of proof (as to the affirmative defense) squarely upon the defendant. *See* ***Natchez Elec. & Supply Co., Inc. v. Johnson,*** 968 So. 2d 358, 361 (Miss. 2007) ("The burden of proving an affirmative defense lies upon the party who relies upon that defense." (*citing* ***Jenkins v. Pensacola Health Trust, Inc.,*** 933 So. 2d 923, 927 (Miss. 2006))).

P76. Franklin argues that the jury instructions were contradictory and did not properly instruct the jury on its affirmative defense. The instructions which were given address the plaintiffs' burden of proof in establishing the causes of action pending before the circuit court. The instructions (recited in the majority opinion) addressing those causes of action were, in my judgment, correct. The fact that the jury was not instructed exactly as Franklin thinks it should have been should not **[**82]** be viewed as error on the part of the plaintiffs, who had no duty to offer an instruction from Franklin's perspective.

P77. That said, under the facts of this case (as discussed by the majority), any additional instruction offered by Franklin wouldn't have affected the outcome anyway. But in the interest of completeness, I offer this analysis which I believe to be complementary -- rather than contrary -- to the majority.

WALLER, C.J., CARLSON, P.J., RANDOLPH, LAMAR AND PIERCE, JJ., JOIN THIS OPINION.

1-Bromopropane (n-Propyl Bromide)

1-Bromopropane can harm the reproductive system and the nervous system. It causes sterility in both male and female test animals, and harms the developing fetus when tested in pregnant animals. 1-Bromopropane can damage the nerves, causing weakness, pain, numbness, and paralysis. It will soon be tested in animals to find out if it can cause cancer, as many similar chemicals do. The effects of 1-bromopropane on human health have not been well studied. However, a few human case reports suggest that 1-bromopropane can harm the nervous system. 1-Bromopropane is a new solvent intended to replace solvents like trichloroethane and some Freons that damage the upper ozone layer. HESIS is issuing this Hazard Alert because 1-bromopropane is being considered for widespread use and is not regulated to protect workers, consumers, or the environment.

Health Hazard ALERT

How to find out if you are working with 1-bromopropane

1-Bromopropane is a solvent. It might be used wherever there is a need to dissolve fats, waxes, or resins. So far, two of its main uses are in degreasing and in spray adhesives. It is being considered for use in drycleaning and for many other uses as a replacement for other organic solvents that damage the upper ozone layer.

Your employer must tell you if you are working with 1-bromopropane, and must train you to use it safely (California Code of Regulations, Title 8, Sections 3203 and 5194). If you think you may be exposed to 1-bromopropane on the job, ask to see the Material Safety Data Sheets (MSDSs) for the products you are using. The MSDS for a product that contains 1-bromopropane must identify it in Section 2, by the CAS number 106-94-5. 1-Bromopropane is also called n-propyl bromide. Some MSDSs do not fully describe the hazards of the product.

How 1-bromopropane enters your body

1-Bromopropane enters your body when you breathe its vapor or drops of spray in the air. Some can enter your body through your skin.

Your risk of health effects depends on the amount of 1-bromopropane that enters your body. That depends mainly on the amount (the concentration) of 1-bromopropane in the air, your skin contact, and how long you are exposed.

How 1-bromopropane can affect your health

The toxic effects of 1-bromopropane in humans have not yet been well studied. Because it is a recently introduced chemical, most information comes from animal testing, not from experience with human use.

In most of the animal tests, the animals breathed 1-bromopropane in the air. However, you can also absorb 1-bromopropane through your skin.

HEALTH HAZARD ALERT
HESIS
HAZARD EVALUATION SYSTEM & INFORMATION SERVICE
California Department of Health Services
Occupational Health Branch
1515 Clay Street, Suite 1901, Oakland, CA 94612
510-622-4300 • www.dhs.ca.gov/ohb

JULY 2003

California Department of Health Services • California Department of Industrial Relations

REPRODUCTIVE SYSTEM

1-Bromopropane damages the reproductive systems in both male and female animals. In males, it damages the sperm, testicles, prostate, epididymis, and seminal vesicles, and reduces testosterone levels, causing sterility. In females, it damages the ovaries and interferes with the estrous cycle, again causing sterility. 1-Bromopropane also caused delayed growth in the offspring of animals exposed during pregnancy. Some of these effects were seen at exposure levels as low as 200 parts per million (200 "ppm") in air, and possibly even at 100 ppm.

Reproductive toxicity of 1-bromopropane has not been studied in humans, but the closely related chemical 2-bromopropane has been found to cause long-lasting ovarian failure and absence of sperm in workers.

NERVOUS SYSTEM

1-Bromopropane damages the nerves in the arms, legs, and body. There is evidence that 1-bromopropane may also damage the brain itself. Animal tests have found these effects with exposures as low as 400 ppm. Case reports show that similar effects can occur in humans.

EYES, NOSE, THROAT, AND SKIN

1-Bromopropane is irritating to the eyes, nose, and throat, at exposure levels of perhaps 30 ppm. Like other organic solvents, the liquid can dissolve the natural protective oils on your skin and cause dermatitis (dry, rough, red, cracked skin). It can also be absorbed into your body through the skin.

LIVER

Very high exposures may harm the liver. We don't know whether there's any risk to the liver from exposure levels likely to be found in the workplace.

CANCER

1-Bromopropane will soon be tested to see whether it can cause cancer. Many similar chemicals, such as dibromochloropropane (DBCP), do cause cancer. In some tests, but not in others, 1-bromopropane has caused genetic mutations. Chemicals that cause mutations often can cause cancer.

HOW TO REDUCE YOUR EXPOSURE

Even though there is no Permissible Exposure Limit (PEL) for 1-bromopropane (see page 4), Cal/OSHA's Title 8, Section 5141 requires your employer to protect you from being exposed to chemicals at levels that harm your health. See www.dir.ca.gov/title8/5141.html.

Cal/OSHA and the Cal/OSHA Consultation Service can help you and your employer – see "Where to Get Help" on the last page.

- **Substitution.** The best way to reduce exposure is to switch to products that don't contain 1-bromopropane. Avoid using products for which you do not have an MSDS.

  Switch to water-based adhesives, when possible, for flexible foam fabrication. Hot water-based aqueous cleaning detergents often can be substituted for 1-bromopropane products for vapor degreasing and cold cleaning operations.

  If you can't switch to 1-bromopropane-free products, take other steps to limit your exposure.

- **Using Less.** If you must use 1-bromopropane products, use as little as possible. Keep containers closed between uses. 1-Bromopropane can evaporate from 1-bromopropane-soaked rags, so make sure that used rags are kept in a well-ventilated area or sealed in an airtight container.

- **Ventilation.** Make sure that there is good ventilation. "Local exhaust ventilation" is most effective; it captures contaminated air at the source, before 1-bromopropane can spread into your breathing zone. In a study conducted by the National Institute for Occupational Safety and Health (NIOSH), for example, improving the local exhaust ventilation reduced 1-bromopropane levels by about 70% in a cushion manufacturing plant. Next best is general ventilation, which uses a fan-powered system to bring fresh air into the work area. Open doors and windows usually provide very little ventilation. An indoor fan that just blows contaminated air around without removing it from your work area is not effective.

- **Other Engineering Controls.** Vapor degreasing systems should include controlled hoists, effective cooling coils, and lids. Vapor degreasing should be isolated from other work areas. If parts are removed wet, the drying area should be vented to the outdoors.

- **Respiratory Protection.** Respirators may be used only if ventilation and other control methods are not effective and feasible. A half-face respirator with organic vapor cartridge can reduce your exposure. In spraying operations, this should be combined with a mist pre-filter cartridge. A "dust mask" will not protect you, and may even increase your exposure by giving a false sense of confidence. Employers must comply with the Cal/OSHA Respiratory Protection Standard (Title 8, Section 5144). See www.dir.ca.gov/title8/5144.html.

- **Skin Protection.** It may be hard to avoid getting 1-bromopropane on your hands if you use it for cleaning or gluing. If you must use 1-bromopropane products and it is likely that it will get on your skin, wear protective gloves and replace them often. Chemical protective clothing, such as aprons or sleeves, may also be needed if skin contact occurs at areas other than your hands. California regulation (Title 8, Section 3384) requires employers to supply gloves or any other necessary protective equipment. Viton, Silvershield, and 4H glove materials may resist penetration by 1-bromopropane longer than most other materials. 1-Bromopropane can penetrate some common glove materials within 30 minutes to two hours.

Legal exposure limits

1-Bromopropane is a virtually unregulated chemical. Cal/OSHA does not have a Permissible Exposure Limit (PEL) for workplace exposure. Neither the U.S. Environmental Protection Agency (U.S. EPA) nor Cal/EPA has set any limits on 1-bromopropane in the environment. U.S. EPA is considering approving 1-bromopropane for use as an alternative to chemicals that damage the ozone layer in the upper atmosphere.

Recommended exposure limits

HESIS recommends that workplace exposure be limited to about 1 ppm in order to protect against the reproductive and nerve toxicity of 1-bromopropane. HESIS also recommends a skin notation to require protection against skin contact exposure.

Many manufacturers and distributors have made recommendations for occupational exposure limits. These proposals range from 5 ppm to 100 ppm.

Measuring your exposure

The amount of 1-bromopropane in the air in your workplace can and should be measured. However, until 1-bromopropane is regulated by Cal/OSHA, there may not be any legal standard to compare the results to.

Are there medical tests for exposure and health effects?

1-Bromopropane levels in urine reflect recent exposure fairly accurately, but the test is difficult and expensive. Bromine levels in urine also reflect recent exposure, but other exposures may influence the test. Standard tests for reproductive function, nervous system damage, and blood effects may be appropriate if you work with 1-bromopropane.

Regulations that help to protect workers

HAZARD COMMUNICATION STANDARD. Under this standard (Title 8, Section 5194), your employer must tell you if any hazardous substances are used in your work area, must train you to use them safely, and must make MSDSs available. See **www.dir.ca.gov/title8/5194.html**.

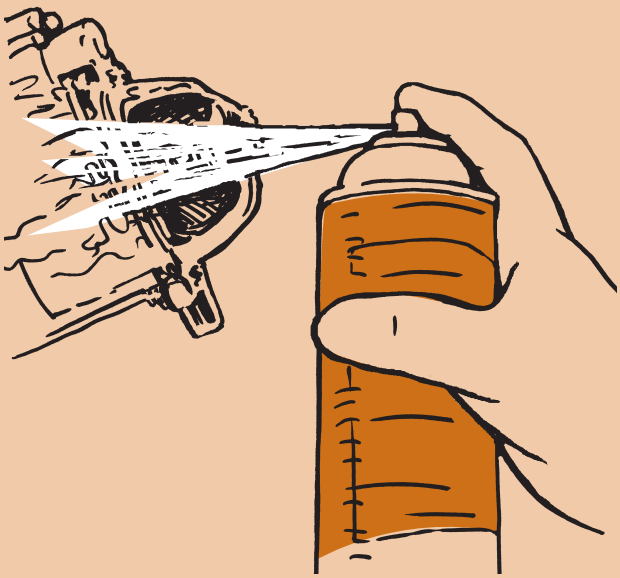
INJURY AND ILLNESS PREVENTION PROGRAM. Every employer must have an effective, written Injury and Illness Prevention Program (IIPP) that identifies a person with the authority and responsibility to run the program (Title 8, Section 3203). The IIPP must include methods for identifying workplace hazards, methods for correcting hazards quickly, health and safety training at specified times, a system for communicating clearly with all employees about health and safety matters (including safe ways for employees to tell the employer about hazards), and record-keeping to document the steps taken to comply with the IIPP Standard. See **www.dir.ca.gov/title8/3203.html**.

ACCESS TO MEDICAL AND EXPOSURE RECORDS. You have the right to see and copy your own medical records, and any records of toxic substance exposure monitoring (Title 8, Section 3204). These records are important in determining whether your health has been affected by your work. Employers who have such records must keep them and make them available to you for at least 30 years after the end of your employment. See **www.dir.ca.gov/title8/3204.html**.

DO YOU USE ANY OF THESE PRODUCTS?

Abzol
Albatross VDS-3000
Alpha Metals VaporEdge 1000
Amrep Misty Safety Solvent 2000
Ceramichrome Overglazes 6, 8, 9, or 18
Ecolink Hypersolve
Ecolink Triagen
EnSolv; EnSolv-A; EnSolv-CW
Hypersolve NPB; Hypersolve ASC
K-Grip 501 Spray Adhesive
Leksol
LPS Instant Super Degreaser II
Micro Care PowrClean Solvent
NPB Heavy Duty Cleaner Degreaser
NPB Heavy Duty Contact Cleaner
NPB Heavy Duty Flux Remover
Nye Lubricants Fluorosolvent 507
Nye Lubricants Nyetact 502H-20
Pensolve PB2000
Petroferm Lenium
Petroferm nPB Stabilizer Booster
Rite-Off Generation 2000 Bromo-Clean
Solvon PB, PBA, AER, ACS, DR, or IP
Techtride DG
Tek-Rap Series 200-20D Low-VOC/HAPs Liquid Adhesive Coating
United C174 Aerosol Contact Cleaner
Western Chemical

These are some products with MSDSs showing that they contain 1-bromo-propane. However, products like these can change their ingredients quite often. Be sure to check the current MSDS for whatever products you're using.



WHERE TO GET HELP

➤ **HESIS** answers questions about 1-bromopropane and other workplace hazards and has many free publications available.

For information on workplace hazards: **(510) 622-4317**. Please leave a message and your call will be returned.

For HESIS Publications: **(510) 622-4138**. Call, or visit our website www.dhs.ca.gov/ohb, or write to HESIS, 1515 Clay Street, Suite 1901, Oakland, CA 94612.

- *HESIS Guide to Solvent Safety.* Discusses health and safety hazards and protective measures.
- *Workplace Chemical Hazards to Reproductive Health: A Resource for Worker Health and Safety Training and Patient Education.* Explains how chemicals can affect reproduction.
- *HESIS Publication List.* Fact sheets, booklets, and medical guidelines on workplace hazards including chemicals, repetitive motion, and infectious diseases. Visit our website, call, or write for the list.

➤ **California Division of Occupational Safety and Health (Cal/OSHA)** investigates workers' complaints, makes enforcement inspections, and answers questions about workplace health and safety regulations. Complainants' identities are kept confidential. Contact the Cal/OSHA Enforcement District office nearest to your workplace. Offices are listed in the blue government section near the front of the phone book, under "State Government / Industrial Relations / Occupational Safety and Health / Enforcement," or visit their website at www.dir.ca.gov/DOSH/districtoffices.htm.

➤ **Other resources for employees** may include your supervisor, your union, your company health and safety officer, your doctor, or your company doctor.

➤ **Cal/OSHA Consultation Service** helps employers who want free, non-enforcement help to evaluate the workplace and improve the health and safety conditions. Employers can call **(800) 963-9424**.

➤ **Occupational health services** can be found at:

- UC San Francisco/SFGH Occupational and Environmental Medicine Clinic: (415) 885-7580.
- UC Davis Occupational and Environmental Medicine Clinic: (530) 754-7635.
- UC Irvine Center for Occupational and Environmental Health: (949) 824-8641.
- UC San Diego Center for Occupational and Environmental Medicine: (619) 471-9210.

Gray Davis, Governor
State of California

Grantland Johnson, Secretary
Health and Human Services Agency

Diana M. Bontá, R.N., Dr.P.H.
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Steve Smith, Acting Secretary
Labor and Workforce Development Agency

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OSP 03 79401

Division of Occupational Safety and Health
N.C. Department of Labor
1101 Mail Service Center
Raleigh, North Carolina 27699-1101

Cherie K. Berry
Commissioner

HEALTH HAZARD ALERT

1-Bromopropane (n-Propyl Bromide)

1-Bromopropane (1-BP) is a new solvent that is effective in dissolving fats, waxes and resins. Two of its main uses are in degreasing agents and in spray adhesives. 1-BP is being used in the furniture industry and as a solvent for adhesives used in constructing foam cushions. The dry cleaning industry, among others, has considered using 1-BP as a replacement for other organic solvents that damage the ozone layer in the upper atmosphere.

The N.C. Department of Labor's Division of Occupational Safety and Health (OSH), is very concerned about the health effects of 1-bromopropane. OSH is issuing this health hazard alert because 1-bromopropane is being considered for widespread use and is not regulated to protect workers, consumers or the environment. North Carolina does not currently have a permissible exposure limit for 1-bromopropane. The American Conference of Governmental Industrial Hygienists recently published a recommended time-weighted average threshold limit value of 10 parts per million, which is equivalent to 50 milligrams of 1-bromopropane (1-BP) per cubic meter of air.[1]

Hazards: 1-Bromopropane can harm both the nervous system and the reproductive system. It can damage the nervous system by interfering with nerve conduction, resulting in limb weakness, pain, numbness, and paralysis.[2,3] It can cause reduced fertility and/or sterility in test animals, both male and female, and it can harm the developing fetus in pregnant female test animals. It will soon be tested to find out if it can cause cancer, as many similar chemicals do. Other harmful effects include irritation of the eyes and skin.[4]

Health Effects

1-Bromopropane enters your body when you breathe its vapor or drops of spray in the air. It can also enter through your skin and cause significant problems, depending on the concentration of 1-BP in the air, your skin contact and exposure time. The toxic effects of 1-bromopropane in humans have not yet been well studied. Because it is a recently introduced chemical, most information comes from animal testing and not from experience with human use. In most of the animal tests, the animals were exposed to 1-bromopropane by breathing it in the air. The following outlines health effects that have been studied.

Reproductive System

1-Bromopropane damages the reproductive systems in both male and female animals. In males, it damages the sperm, testicles, prostate, epididymis and seminal vesicles and reduces testosterone levels, causing sterility. In females, it damages the ovaries and interferes with the estrous cycle, again causing sterility. 1-Bromopropane also caused delayed growth in the offspring of animals exposed during pregnancy. Some of these effects were seen at exposure levels as low as 200 ppm in the air, and possibly even at 100 ppm. The reproductive toxicity of 1-bromopropane has not been studied in humans, but 2-bromopropane, a closely related chemical, has been found to cause long-lasting ovarian failure and absence of sperm in workers.

Nervous System

1-Bromopropane damages the nerves in the arms, legs and body. There is evidence that 1-bromopropane may also damage the brain. Animal tests have found these effects with exposures as low as 400 ppm. Case reports show that similar effects can occur in humans.

Eyes, Nose, Throat and Skin

1-Bromopropane is irritating to the eyes, nose and throat at exposure levels of perhaps 30 ppm. Like other organic solvents, the liquid can dissolve the natural protective oils on skin and cause dermatitis (dry, rough, red, cracked skin).

Liver

Very high exposures may harm the liver. It is not known whether exposure levels likely to be found in the workplace present any risks to the liver.

Cancer

1-Bromopropane will soon be tested to see whether it can cause cancer. Many similar chemicals, such as dibromochloropropane, do cause cancer. In some tests, but not in others, 1-bromopropane has caused genetic mutations. Chemicals that cause mutations can often cause cancer as well.

1,000 copies of this public document were printed at a cost of $29, or $.03 per copy.

How to Reduce Health Risks

- **Substitution.** The best way to reduce exposure is to switch to products that do not contain 1-bromopropane.
- **Using less.** If 1-bromopropane products must be used, quantities should be kept as small as possible, and containers should be kept closed between uses.
- **Other engineering controls.** Vapor degreasing systems should include controlled hoists, effective cooling coils and lids.
- **Ventilation.** Make sure that there is good ventilation. Local exhaust ventilation is most effective because it captures contaminated air at the source.
- **Personal protective equipment.** Aprons, gloves, goggles and respirators approved for use with organic chemicals can be effective in helping workers avoid exposure.
- **Respiratory protection.** Respirators may be used only if ventilation and other control methods are not effective and feasible.

Requirements for Employers: Even if a chemical is not regulated by an OSH standard, employers are still required to "furnish … conditions of employment and a place of employment free from recognized hazards." Employers also must ensure that employees do not suffer illness or injury from the use of any chemical agent.

Rights of Employees: If you think you may be exposed to 1-bromopropane on the job, ask to see the material safety data sheets (MSDS) for the products you are using. The MSDS for a product that contains 1-bromopropane must identify it in Section 2, by the CAS number 106-94-5. 1-Bromopropane is also called n-propyl bromide. Some MSDSs do not fully describe the hazards of the product. Your employer must tell you if you are working with 1-bromopropane and must train you to use it safely (ref. Hazard Communication Standard, Subpart Z 1910.1200, Toxic and Hazardous Substances).

Copies of safety and health standards for 29 CFR 1910 (General Industry) and 29 CFR 1926 (Construction) are available from NCDOL/ETTA upon request. Publications can also be ordered online (www.nclabor.com).

For more information concerning education, training and interpretations of occupational safety and health standards contact:

Bureau of Education, Training and Technical Assistance
Fourth Floor, Old Revenue Building, Raleigh N.C.
Telephone: (919) 807-2875 Fax: (919) 807-2876

For more information concerning occupational safety and health consultative services and safety awards programs contact:

Bureau of Consultative Services
Third Floor, Old Revenue Building, Raleigh, N.C.
Telephone: (919) 807-2899 Fax: (919) 807-2902

Mailing Address: 1101 Mail Service Center, Raleigh NC 27699-1101

N.C. Department of Labor Web Site: http://www.nclabor.com

Toll Free Number: 1-800-NC-LABOR (1-800-625-2267)

Information Sources: The information provided in this alert is derived in part from a hazard alert issued by the California Department of Health Services, California Department of Industrial Relations**.** The source document (printed July 2003) as referenced here is used with permission granted by HESIS. (Source: Hazard Evaluation System and Information Service (HESIS), California Department of Health Services, Occupational Health Branch, 1515 Clay Street, Suite 1901, Oakland, CA 94612; (510) 622-4300; www.dhs.ca.gov/ohb.)

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1. American Conference of Governmental Industrial Hygienists, 2005.
2. Yu, et al. Preliminary Report on the Neurotoxicity of 1-Bromopropane, an Alternative Solvent for Chlorofluorocarbons, J. Occup Health 1998; 40:234-235.
3. Ichihara, et al. Neurological Disorders in Three Workers Exposed to 1-Bromopropane, J. Occup Health 2002; 44:1-7.
4. ICSC:1332, International Programme on Chemical Safety and the Commission of the European Communities.

72 FR 30168, *

FEDERAL REGISTER

Vol. 72, No. 103

Proposed Rules

ENVIRONMENTAL PROTECTION AGENCY (EPA)

40 CFR Part 82

[EPA-HQ-OAR-2002-0064; FRL-8316-7]

RIN 2060-AK26

Protection of Stratospheric Ozone: Listing of Substitutes for Ozone-Depleting Substances--n-Propyl Bromide in Adhesives, Coatings, and Aerosols

72 FR 30168

DATE: Wednesday, May 30, 2007

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Pursuant to the U.S. Environmental Protection Agency's (EPA or "we") Significant New Alternatives Policy (SNAP) program, this action proposes to list n-propyl bromide (nPB) as an unacceptable substitute for methyl chloroform, chlorofluorocarbon (CFC)-113, and hydrochlorofluorocarbon (HCFC)-141b when used in adhesives or in aerosol solvents because nPB in these end uses poses unacceptable risks to human health when compared with other substitutes that are available. In addition, EPA takes comment on alternate options that would find nPB acceptable subject to use conditions in adhesives or in aerosol solvents. This action also proposes to list nPB as acceptable, subject to use conditions, as a substitute for methyl chloroform, CFC-113, and hydrochlorofluorocarbon (HCFC)-141b in the coatings end use. This proposal supersedes EPA's proposal of June 3, 2003 on the acceptability of nPB as a substitute for ozone-depleting substances for aerosols and adhesives.

DATES: Comments must be received in writing by July 30, 2007. Under the Paperwork Reduction Act, comments on the information collection provisions must be received by the Office of Management and Budget (OMB) on or before June 29, 2007. Any person interested in requesting a public hearing, must submit such request on or before June 29, 2007. If a public hearing is requested, a separate notice will be published announcing the date and time of the public hearing and the comment period will be extended until 30 days after the public hearing to allow rebuttal and supplementary information regarding any material presented at the public hearing. Inquiries regarding a public hearing should be directed to the contact person listed below.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2002-0064, by one of the following methods:

. *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

. *E-mail: A-And-R-Docket@epa.gov.*

. *Mail:* Air and Radiation Docket, Environmental Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington DC 20460, Attention Docket ID No. EPA-HQ-OAR-2002-0064. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *Attn:* Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.

. *Hand Delivery:* EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. EPA-HQ-OAR-2002-0064. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OAR-2002-0064. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I.B. of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov index.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air and Radiation Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Margaret Sheppard, Stratospheric Protection Division, Office of Atmospheric Programs, Mail Code 6205J, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number (202) 343-9163; fax number (202) 343-2362 e-mail address: *sheppard.margaret@epa.gov.* Notices and rulemakings under the SNAP program are available on EPA's Stratospheric Ozone World Wide Web site at *http://www.epa.gov/ozone/snap/regs.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

A. Does this action apply to me?

This proposed rule would regulate the use of n-propyl bromide as an aerosol solvent and as a carrier solvent in adhesives and coatings. Businesses in these end uses that currently might be using nPB, or might want to use it in the future, include:

. Businesses that manufacture electronics or computer equipment.

. Businesses that require a high level of cleanliness in removing oil, grease, or wax, such as for aerospace applications or for manufacture of optical equipment.

. Foam fabricators that glue pieces of polyurethane foam together or foam cushion manufacturers that glue fabric around a cushion.

. Furniture manufacturers that use adhesive to attach wood parts to floors, tables and counter tops.

. A company that manufactures ammunition for the U.S. Department of Defense. Regulated entities may include:

Table 1.--Potentially Regulated Entities, by North American Industrial Classification System (NAICS) Code or Subsector

Category	NAICS code or subsector	Description of regulated entities
Industry	331	Primary Metal Manufacturing.
Industry	332	Fabricated Metal Product Manufacturing.
Industry/Military	332992	Small Arms Ammunition Manufacturing.
Industry	333	Machinery Manufacturing.
Industry	334	Computer and Electronic Product Manufacturing.
Industry	335	Equipment Appliance, and Component Manufacturing.
Industry	336	Transportation Equipment Manufacturing.
Industry	337	Furniture and Related Product Manufacturing.
Industry	339	Miscellaneous Manufacturing.
Industry	326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing.

This table is not intended to be exhaustive, but rather a guide regarding entities likely to be regulated by this action. If you have any questions about whether this action applies to a particular entity, consult the person listed in the preceding section, **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. Submitting Confidential Business Information (CBI). Do not submit this information to EPA through *www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for Preparing Your Comments. When submitting comments, remember to:

. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** (FR) date and page number).

. Follow directions--The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

. Describe any assumptions and provide any technical information and/or data that you used.

. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

. Provide specific examples to illustrate your concerns, and suggest alternatives.

. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

. Make sure to submit your comments by the comment period deadline identified.

C. What acronyms and abbreviations are used in the preamble?

Below is a list of acronyms and abbreviations used in this document.

8-hr--eight hour

ACGIH--American Conference of Governmental Industrial Hygienists

AEL--acceptable exposure limit **[*30170]**

ASTM--American Society for Testing and Materials

BMD--benchmark dose

BMDL--benchmark dose lowerbound, the lower 95%-confidence level bound on the dose/exposure associated with the benchmark response

BSOC--Brominated Solvents Consortium

CAA--Clean Air Act

CAS Reg. No--Chemical Abstracts Service Registry Identification Number

CBI--Confidential Business Information

CEG--community exposure guideline

CERHR--Center for the Evaluation of Risks to Human Reproduction

CFC-113--the ozone-depleting chemical 1,1,2-trifluoro-1,2,2-trichloroethane, C[2] Cl[3] F[3], CAS Reg. No. 76-13-1

CFC--chlorofluorocarbon

cfm--cubic feet per minute

CFR--Code of Federal Regulations

CNS--central nervous system

DNA--deoxyribonucleic acid

EDSTAC--The Endocrine Disruptor Screening and Testing Advisory Committee

EPA--the United States Environmental Protection Agency

FR--Federal Register

GWP--global warming potential

HCFC-141b--the ozone-depleting chemical 1,1-dichloro-1-fluoroethane, CAS Reg. No. 1717-00-6

HCFC-225ca/cb--the commercial mixture of the two ozone-depleting chemicals 3,3-dichloro-1,1,1,2,2-pentafluoropropane, CAS Reg. No. 422-56-0 and 1,3-dichloro-1,1,2,2,3-pentafluoropropane, CAS Reg. No. 507-55-1

HCFC--hydrochlorofluorocarbon

HEC--human equivalent concentration

HFC-245fa--the chemical 1,1,3,3,3-pentafluoropropane, CAS Reg. No. 460-73-1

HFC-365mfc--the chemical 1,1,1,3,3-pentafluorobutane, CAS Reg. No. 405-58-6

HFC-4310mee--the chemical 1,1,1,2,3,4,4,5,5,5-decafluoropentane, CAS Reg. No. 138495-42-8

HFC--hydrofluorocarbon

HFE--hydrofluoroether

HHE--health hazard evaluation

ICF--ICF Consulting

ICR--Information Collection Request

iPB--isopropyl bromide, C[3] H[7] Br, CAS Reg. No. 75-26-3, an isomer of n-propyl bromide; also called 2-bromopropane or 2-BP

K[oc] --organic carbon partition coefficient, for determining the tendency of a chemical to bind to organic carbon in soil

LC[50] --the concentration at which 50% of test animals die

LOAEL--Lowest Observed Adverse Effect Level

Log K[ow] --logarithm of the octanol-water partition coefficient, for determining the tendency of a chemical to accumulate in lipids or fats instead of remaining dissolved in water

mg/l--milligrams per liter

MSDS--Material Safety Data Sheet

NAICS--North American Industrial Classification System

NIOSH--National Institute for Occupational Safety and Health

NOAEL--No Observed Adverse Effect Level

NOEL--No Observed Effect Level

nPB--ln-propyl bromide, C[3] H[7] Br, CAS Reg. No. 106-94-5; also called 1-bromopropane or 1-BP

NPRM--Notice of Proposed Rulemaking

NTP--National Toxicology Program

NTTAA--National Technology Transfer and Advancement Act

ODP--ozone depletion potential

ODS--ozone-depleting substance

OEHHA--Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency

OMB--U.S. Office of Management and Budget

OSHA--the United States Occupational Safety and Health Administration

PCBTF--parachlorobenzotrifluoride, CAS Reg. No. 98-56-6

PEL--Permissible Exposure Limit ppm-parts per million

RCRA--Resource Conservation and Recovery Act

RFA--Regulatory Flexibility Act

RfC--reference concentration

SIP--state implementation plan

SNAP--Significant New Alternatives Policy

TCA--the ozone-depleting chemical 1,1,1-trichloroethane, CAS Reg. No. 71-55-6; also called methyl chloroform, MCF, or 1,1,1

TCE--the chemical 1,1,2-trichloroethene, CAS Reg. No. 79-01-6, C2Cl3H; also call trichloroethylene

TERA--Toxicological Excellence for Risk Assessment

TLV--Threshold Limit Value(tm)

TSCA--Toxic Substances Control Act

TWA--time-weighted average

UMRA--Unfunded Mandates Reform Act

U.S.C.--United States Code

VMSs--volatile methyl siloxanes

VOC--volatile organic compound

II. How does the Significant New Alternatives Policy (SNAP) program work?

A. What are the statutory requirements and authority for the SNAP program?

Section 612 of the Clean Air Act (CAA) authorizes EPA to develop a program for evaluating alternatives to ozone-depleting substances, referred to as the Significant New Alternatives Policy (SNAP) program. The major provisions of section 612 are:

. *Rulemaking* --Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I (chlorofluorocarbon, halon, carbon tetrachloride, methyl chloroform, and hydrobromofluorocarbon) or class II (hydrochlorofluorocarbon) substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment, and (2) is currently or potentially available.

. *Listing of Unacceptable/Acceptable Substitutes* --Section 612(c) also requires EPA to publish a list of the substitutes unacceptable for specific uses. We must publish a corresponding list of acceptable alternatives for specific uses.

. *Petition Process* --Section 612(d) grants the right to any person to petition EPA to add a substitute to or delete a substitute from the lists published in accordance with section 612(c). EPA has 90 days to grant or deny a petition. Where the Agency grants the petition, we must publish the revised lists within an additional six months.

. *90-day Notification* --Section 612(e) requires EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's health and safety studies on such substitutes.

. *Outreach* --Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.

. *Clearinghouse* --Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use class I and II substances.

B. How do the regulations for the SNAP program work?

On March 18, 1994, EPA published the original rulemaking (59 FR 13044) that described the process for administering the SNAP program and issued the first acceptability lists for substitutes in the major industrial use sectors. These sectors include: Refrigeration and air conditioning; foam blowing; solvents cleaning; fire suppression and explosion protection; sterilants; aerosols; adhesives, coatings and inks; and tobacco expansion. These sectors comprise the principal industrial sectors that historically consumed large volumes of ozone-depleting substances.

Anyone who plans to market or produce a substitute for an ozone-depleting substance (ODS) in one of the eight major industrial use sectors must provide the Agency with health and safety studies on the substitute at least 90 days before introducing it into **[*30171]** interstate commerce for significant new use as an alternative. This requirement applies to the person planning to introduce the substitute into interstate commerce, typically chemical manufacturers, but may also include importers, formulators or end-users when they are responsible for introducing a substitute into commerce.

The Agency has identified four possible decision categories for substitutes: Acceptable; acceptable subject to use conditions; acceptable subject to narrowed use limits; and unacceptable. Use conditions and narrowed use limits are both considered "use restrictions" and are explained below. Substitutes that are deemed acceptable with no use restrictions (no use conditions or narrowed use limits) can be used for all applications within the relevant sector end-use. Substitutes that are acceptable subject to use restrictions may be used only in accordance with those restrictions. It is illegal to replace an ODS with a substitute listed as unacceptable.

After reviewing a substitute, the Agency may make a determination that a substitute is acceptable only if certain conditions of use are met to minimize risks to human health and the environment. We describe such substitutes as "acceptable subject to use conditions." If you use these substitutes without meeting the associated use conditions, you use these substitutes in an unacceptable manner and you could be subject to enforcement for violation of section 612 of the Clean Air Act.

For some substitutes, the Agency may permit a narrowed range of use within a sector. For example, we may limit the use of a substitute to certain end-uses or specific applications within an industry sector or may require a user to demonstrate that no other acceptable end uses are available for their specific application. We describe these substitutes as "acceptable subject to narrowed use limits." If you use a substitute that is acceptable subject to narrowed use limits, but use it in applications and end-uses which are not consistent with the narrowed use limit, you are using these substitutes in an unacceptable manner and you could be subject to enforcement for violation of section 612 of the Clean Air Act.

The Agency publishes its SNAP program decisions in the **Federal Register** . For those substitutes that are deemed acceptable subject to use restrictions (use conditions and/or narrowed use limits), or for substitutes deemed unacceptable, we first publish these decisions as proposals to allow the public opportunity to comment, and we publish final decisions as final rulemakings. In contrast, we publish substitutes that are deemed acceptable with no restrictions in "notices of acceptability," rather than as proposed and final rules. As described in the rule implementing the SNAP program (59 FR 13044), we do not believe that rulemaking procedures are necessary to list alternatives that are acceptable without restrictions because such listings neither impose any sanction nor prevent anyone from using a substitute.

Many SNAP listings include "comments" or "further information." These statements provide additional information on substitutes that we determine are unacceptable, acceptable subject to narrowed use limits, or acceptable subject to use conditions. Since this additional information is not part of the regulatory decision, these statements are not binding for use of the substitute under the SNAP program. However, regulatory requirements listed in this column are binding under other programs. The further information does not necessarily include all other legal obligations pertaining to the use of the substitute. However, we encourage users of substitutes to apply all statements in the "Further Information" column in their use of these substitutes. In many instances, the information simply refers to sound operating practices that have already been identified in existing industry and/or building-code standards. Thus, many of the comments, if adopted, would not require the affected industry to make significant changes in existing operating practices.

C. Where can I get additional information about the SNAP program?

For copies of the comprehensive SNAP lists of substitutes or additional information on SNAP, look at EPA's Ozone Depletion World Wide Web site at *http://www.epa.gov/ozone/snap/lists/index.html.* For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the SNAP final rulemaking published in the **Federal Register** on March 18, 1994 (59 FR 13044), codified at Code of Federal Regulations at 40 CFR part 82, subpart G. You can find a complete chronology of SNAP decisions and the appropriate **Federal Register** citations at *http://www.epa.gov/ozone/snap/chron.html.*

III. What is EPA proposing today?

In this action, EPA proposes to list n-propyl bromide (nPB) as (1) unacceptable for use as a substitute for CFC-113, n1 methyl chloroform n2 and HCFC-141b n3 in the adhesive and aerosol solvent end uses; and (2) acceptable subject to use conditions (limited to coatings at facilities that, as of May 30, 2007, have provided EPA with information demonstrating their ability to maintain acceptable workplace exposures) as a substitute for methyl chloroform, CFC-113, and HCFC-141b in the coatings end use. This Notice of Proposed Rulemaking (NPRM) supersedes the NPRM published on June 3, 2003 (68 FR 33284) for aerosol solvents and adhesives.

n1 CFC-113 is also referred to as Freon-113, or 1,1,2-trifluoro-1,2,2-trichloroethane. Its CAS Reg. No. is 76-13-1.

n2 Methyl chloroform is also referred to as 1,1,1-trichloroethane, TCA, MCF, or 1,1,1. Its CAS Reg. No. is 71-55-6.

n3 HCFC-141b is also referred to as 1,1-dichloro-1-fluoroethane. Its CAS Reg. No. is 1717-00-6.

A. What is n-propyl bromide?

n-propyl bromide (nPB), also called 1-bromopropane, is a non-flammable organic solvent with a strong odor. Its chemical formula is C[3] H[7] Br. Its identification number in Chemical Abstracts Service's registry (CAS Reg. No.) is 106-94-5. nPB is used to remove wax, oil, and grease from electronics, metal, and other materials. It also is used as a carrier solvent in adhesives. Some brand names of products using nPB are: Abzol(R), EnSolv(R), and Solvon(R) cleaners; Pow-R-Wash(R) NR Contact Cleaner, Superkleen Flux Remover 2311 and LPS NoFlash NU Electro Contact Cleaner aerosols; and Whisper Spray and Fire Retardant Soft Seam 6460 adhesives.

B. What industrial end uses are included in our proposed decision?

This proposal addresses the use of n-propyl bromide in the aerosol solvent end use of the aerosol sector and the adhesives and coatings end uses in the adhesives, coatings, and inks sector as discussed below. EPA is issuing a decision on the use of nPB in metals, electronics, and precision cleaning in a separate final rule. EPA has insufficient information for ruling on other end uses or sectors where nPB might be used (e.g., inks, foam blowing, fire suppression).

1. Aerosol Solvents

We understand that nPB is being used as an aerosol solvent in:

. Lubricants, coatings, or cleaning fluids for electrical or electronic equipment;

Lubricants, coatings, or cleaning fluids for aircraft maintenance; or **[*30172]**

. Spinnerrette lubricants and cleaning sprays used in the production of synthetic fibers.

2. Adhesives

Types of adhesives covered under the SNAP program are those that formerly used methyl chloroform, specifically, adhesives for laminates, flexible foam, hardwood floors, tire patches, and metal to rubber

adhesives. Of these applications, nPB-based adhesives have been used most widely in spray adhesives used in manufacture of foam cushions, and to a lesser degree in laminate adhesives.

3. Coatings

The SNAP program regulates the use of carrier solvents in durable coatings, including paints, varnishes, and aerospace coatings (59 FR 13118). The SNAP program currently does not regulate carrier solvents in lubricant coatings, such as silicone coatings used on medical equipment (59 FR 13119). Methyl chloroform has been used as a carrier solvent in coatings, and to a much lesser degree, HCFC-141b also has been a carrier solvent. This rule responds to a submission from a facility that is substituting methyl chloroform with nPB as an ammunition coating (sealant).

C. What is the proposed text for EPA's listing decisions?

In the proposed regulatory text at the end of this document, you will find our proposed decisions for those end uses for which we have proposed nPB as unacceptable or acceptable subject to use conditions. The proposed conditions listed in the "Use Conditions" column would be enforceable while information contained in the "Further Information" column of those tables provides additional recommendations on the safe use of nPB. Our proposed decisions for each end use are summarized below in tables 2 through 4.

Proposed Listings

Table 2.--Aerosols
Proposed
Unacceptable
Substitutes

End Use	Substitute	Decision	Further information
Aerosol solvents	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Unacceptable	EPA finds unacceptable risks to human health in this end use compared to other available alternatives. nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.

Table 3.--Adhesives, Coatings, and Inks
Proposed
Unacceptable
Substitutes

Enduse	Substitute	Decision	Further information
Adhesives	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Unacceptable	EPA finds unacceptable risks to human health in this end use compared to other available

Table 3.--Adhesives, Coatings, and Inks Proposed Unacceptable Substitutes

Enduse	Substitute	Decision	Further information
			alternatives. nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.

Table 4.--Adhesives, Coatings, and Inks Substitutes That Are Proposed Acceptable Subject to Use Conditions

End Use	Substitute	Decision
Coatings	n-propyl bromide (nPB) as a substitute for methyl chloroform, CFC-113, and HCFC-141b	Acceptable subject to use conditions

Table 4.--Adhesives, Coatings, and Inks Substitutes That Are Proposed Acceptable Subject to Use Conditions

End Use	Use conditions	Further information
Coatings	Use is limited to coatings facilities that, as of May 30, 2007, have provided EPA information demonstrating their ability to maintain acceptable workplace exposures	EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing. EPA expects that all users of nPB would comply with any final Permissible Exposure Limit that the Occupational Safety and Health Administration issues in the future under 42 U.S.C. 7610(a). nPB, also known as 1-

Table 4.--Adhesives, Coatings, and Inks Substitutes That Are Proposed Acceptable Subject to Use Conditions

End Use	Use conditions	Further information
		bromopropane, is Number 106-94-5 in the CAS Registry.

Note: As of May 30, 2007, the Lake City Army Ammunition Plant is the only facility using nPB in coatings that has provided information to EPA that meets this condition.

D. What does an unacceptability determination on adhesives and aerosols mean?

In this action, EPA is proposing to find nPB unacceptable as a substitute for methyl chloroform, CFC-113, and HCFC-141b for use as a carrier solvent in adhesives and as an aerosol solvent. If this proposal were to become final, it would be illegal to use nPB or blends of nPB and other solvents in adhesives or in aerosol solvent formulations as a substitute for ozone-depleting substances.

E. What is the scope of the proposed determination for coatings?

We propose to list nPB as an acceptable substitute, subject to use conditions, for methyl chloroform, CFC-113, and HCFC-141b in coatings for facilities that, as of May 30, 2007, have **[*30173]** provided EPA information demonstrating their ability to maintain acceptable workplace exposures. EPA has received a petition to allow use of nPB for the ammunition coating application at Lake City Army Ammunition Plant. This is the only coatings application or facility for which EPA has exposure and usage data demonstrating an ability to maintain workplace exposure levels below even the minimum level of the range of exposures that EPA is considering to be potentially acceptable (i.e., 17 to 30 ppm) (see section IV.E for an evaluation of the health risks associated with nPB). If other facilities are interested in using nPB as a substitute for methyl chloroform, CFC-113, or HCFC-141b in their coatings application, or if a person wishes to market nPB for such use, then the interested party would need to make a submission under the SNAP program.

IV. What criteria did EPA consider in preparing this proposal?

In the original rule implementing the SNAP program (March 18, 1994; 59 FR 13044, at 40 CFR 82.180(a)(7)), the Agency identified the criteria we use in determining whether a substitute is acceptable or unacceptable as a replacement for class I or II compounds:

(i) Atmospheric effects and related health and environmental impacts;

[e.g., ozone depletion potential]

(ii) General population risks from ambient exposure to compounds with direct toxicity and to increased ground-level ozone;

(iii) Ecosystem risks [e.g., bioaccumulation, impacts on surface and groundwater];

(iv) Occupational risks;

(v) Consumer risks;

(vi) Flammability; and

(vii) Cost and availability of the substitute.

In this review, EPA considered all the criteria above. However, n-propyl bromide is used in industrial applications such as electronics cleaning or spray adhesives used in foam fabrication. In those consumer products made using nPB, such as a piece of furniture or a computer, the nPB would have evaporated long

before a consumer would purchase the item. Therefore, we believe there is no consumer exposure risk to evaluate in the end uses we evaluated for this rule.

Section 612(c) of the Clean Air Act directs EPA to publish a list of replacement substances ("substitutes") for class I and class II ozone depleting substances based on whether the Administrator determines they are safe (when compared with other currently or potentially available substitutes) for specific uses or are to be prohibited for specific uses. EPA must compare the risks to human health and the environment of a substitute to the risks associated with other substitutes that are currently or potentially available. In addition, EPA also considers whether the substitute for class I and class II ODSs "reduces the overall risk to human health and the environment" compared to the ODSs being replaced. Our evaluation is based on the end use; for example, we compared nPB as a carrier solvent in adhesives to other available or potentially available adhesive alternatives.

Although EPA does not judge the effectiveness of an alternative for purposes of determining whether it is acceptable, we consider effectiveness when determining whether alternatives that pose less risk are available in a particular application within an end use. There are a wide variety of acceptable alternatives listed for aerosol solvents, but not all may be appropriate for a specific application because of differences in materials compatibility, flammability, degree of cleanliness required, local environmental requirements, and other factors.

EPA evaluated each of the criteria separately and then considered overall risk to human health and the environment in comparison to other available or potentially available alternatives. We concluded that overall, environmental risks were not sufficient to find nPB unacceptable in any of the evaluated end uses. However, the overall risks to human health, and particularly the risks to worker health, are sufficiently high in the adhesive and aerosol solvent end uses to warrant our proposal to find nPB unacceptable.

A. Availability of Alternatives to Ozone-Depleting Substances

Other alternatives are available in each end use considered in this proposal. Examples of other available alternatives for aerosol solvents that have already been found acceptable or acceptable subject to use conditions under the SNAP program include water-based formulations, alcohols, ketones, esters, ethers, terpenes, HCFC-141b, HCFC-225ca/cb, hydrofluoroethers (HFEs), hydrofluorocarbon (HFC)-4310mee, HFC-365mfc, HFC-245fa, hydrocarbons, trans-1,2-dichloroethylene, methylene chloride, trichloroethylene n4 (TCE), perchloroethylene n5, and parachlorobenzotrifluoride (PCBTF). Of these, hydrocarbons, alcohols, blends of trans-1,2-dichloroethylene and HFEs or HFCs, and HCFC-225ca/cb are most likely to be used in the same applications as nPB. nPB is already commercially available in aerosols. Its use is primarily for electrical contact cleaning, with some use for benchtop cleaning applications (Williams, 2005).

n4 Also called trichlorethene or TCE, C[2] Cl[3] H, CAS Reg. No. 79-01-6.

n5 Also called PERC, tetrachloroethylene, or tetrachloroethene, C[2] Cl[4], CAS Reg. No. 127-18-4.

Many alternatives are also available for use in adhesives, coatings, and inks: Water-based formulations, high solid formulations, alcohols, ketones, esters, ethers, terpenes, HFEs, hydrocarbons, trans-1,2-dichloroethylene, chlorinated solvents, PCBTF, and a number of alternative technologies (e.g., powder, hot melt, thermoplastic plasma spray, radiation-cured, moisture-cured, chemical-cured, and reactive liquid). Of these, the alternative adhesives most likely to be used in the same applications as nPB are water-based formulations, adhesives with methylene chloride, and flammable adhesives with acetone (IRTA, 2000). nPB is already used in adhesives, and particularly in foam fabrication and in constructing seating for aircraft (IRTA, 2000; Seilheimer, 2001).

To our knowledge, nPB is potentially available as a carrier solvent in coatings, but has not yet been commercialized, except for use by one facility, the Lake City Army Ammunition Plant. The Lake City Army Ammunition Plant evaluated twenty-nine carrier solvent alternatives to methyl chloroform and determined that nPB is the only satisfactory alternative for their application given the current process at that facility (Harper, 2005).

B. Impacts on the Atmosphere and Local Air Quality

As discussed in the June, 2003 proposal, nPB emissions from the continental United States are estimated to have an ozone depletion potential (ODP) of approximately 0.013-0.018, (Wuebbles, 2002), lower than that of the ozone depletion potential of the substances that nPB would replace--CFC-113 (ODP = 1.0), and methyl chloroform and HCFC-141b (ODPs = 0.12) (WMO, 2002). Some other acceptable alternatives for these ODSs also have low ODPs. For example, HCFC-225ca/cb has an ODP of 0.02-0.03 (WMO, 2002) and is acceptable as an aerosol solvent. There are other acceptable solvents for aerosols, adhesives, and coatings that essentially have no ODP--aqueous cleaners, HFEs, HFC-4310mee, HFC-365mfc, HFC-245fa, hydrocarbons, volatile methyl siloxanes (VMSs), methylene chloride, TCE, perchloroethylene, and PCBTF. **[*30174]** Based on this information, we do not believe the use of nPB within the U.S., and within the end-uses reviewed in this rulemaking, poses a significantly greater risk to the ozone layer than other available substitutes.

Comments on the June 2003 NPRM expressed concern that other countries, particularly those in equatorial regions, might assume that nPB does not pose a danger to the stratospheric ozone layer if the U.S. EPA's SNAP program finds nPB acceptable (Linnell, 2003; Steminiski, 2003). Because the ODP for nPB is higher when used in the tropics, n6 we recognize the concerns raised by these commenters. However, EPA is regulating use in the U.S. and cannot dictate actions taken by other countries. We believe the more appropriate forum to address this concern is through the Parties to the Montreal Protocol. At the most recent Meeting of the Parties, the Parties made the following decision with regard to n-propyl bromide, in order to "allow Parties to consider further steps regarding n-propyl bromide, in the light of available alternatives" (Decision XVIII/11):

n6 nPB emissions in the tropics have an ODP of 0.071 to 0.100; the portions of the U.S. outside the continental U.S., such as Alaska, Hawaii, Guam, and the U.S. Virgin Islands, contain less than 1 percent of the U.S.'s businesses in industries that could use nPB. Thus, their potential impact on the ozone layer must be significantly less than that of the already low impact from nPB emissions in the continental U.S. (U.S. Economic Census, 2002a through f).

1. To request the Scientific Assessment Panel to update existing information on the ozone depletion potential of n-propyl bromide, including ozone depleting potential depending on the location of the emissions and the season in the hemisphere at that location;

2. To request the Technology and Economic Assessment Panel to continue its assessment of global emissions of n-propyl bromide, * * * paying particular attention to:

(a) Obtaining more complete data on production and uses of n-propyl bromide as well as emissions of n-propyl bromide from those sources;

(b) Providing further information on the technological and economical availability of alternatives for the different use categories of n-propyl bromide and information on the toxicity of and regulations on the substitutes for n-propyl bromide;

(c) Presenting information on the ozone depletion potential of the substances for which n-propyl bromide is used as a replacement;

3. To request that the Technology and Economic Assessment Panel prepare a report on the assessment referred to in paragraph 1 in time for the twenty-seventh meeting of the Open-ended Working Group for the consideration of the Nineteenth Meeting of the Parties. (MOP 18, 2006)

The global warming potential (GWP) index is a means of quantifying the potential integrated climate forcing of various greenhouse gases relative to carbon dioxide. Earlier data found a direct 100-year integrated GWP (100yr GWP) for nPB of 0.31 (Atmospheric and Environmental Research, Inc., 1995). More recent analysis that considers both the direct and the indirect GWP of nPB found a 100-yr GWP of 1.57 (ICF, 2003a; ICF, 2006a). In either case, the GWP for nPB is comparable to or below that of previously approved substitutes in these end uses.

Use of nPB may be controlled as a volatile organic compound (VOC) under state implementation plans (SIPs) developed to attain the National Ambient Air Quality Standards for ground-level ozone, which is a respiratory irritant. Users located in ozone nonattainment areas may need to consider using a substitute for cleaning that is not a VOC or if they choose to use a substitute that is a VOC, they may need to control

emissions in accordance with the SIP. Companies have petitioned EPA, requesting that we exempt nPB from regulation as a VOC. However, unless and until EPA issues a final rulemaking exempting a compound from the definition of VOC and states change their SIPs to exclude such a compound from regulation, that compound is still regulated as a VOC. Other acceptable ODS-substitute solvents that are VOCs for state air quality planning purposes include most oxygenated solvents such as alcohols, ketones, esters, and ethers; hydrocarbons and terpenes; trichloroethylene; trans-1,2-dichloroethylene; monochlorotoluenes; and benzotrifluoride. Some VOC-exempt solvents that are acceptable ODS substitutes include HFC-245fa, HCFC-225ca/cb, HFC-365mfc and HFC-4310mee for aerosol solvents, and methylene chloride, perchloroethylene, HFE-7100, HFE-7200, PCBTF, acetone, and methyl acetate for aerosol solvents, adhesives, and coatings.

C. Ecosystem and Other Environmental Impacts

EPA considered the possible impacts of nPB if it were to pollute soil or water as a waste and compared these impacts to screening criteria developed by the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC, 1998) (see Table 5). Available data on the organic carbon partition coefficient (K[oc]), the breakdown processes in water and hydrolysis half-life, and the volatilization half-life indicate that nPB is less persistent in the environment than many solvents and would be of low to moderate concern for movement in soil. Based on the LC[50], the acute concentration at which 50% of tested animals die, nPB's toxicity to aquatic life is moderate, being less than that for some acceptable cleaners (for example, trichloroethylene, hexane, d-limonene, and possibly some aqueous cleaners) and greater than that for some others (methylene chloride, acetone, isopropyl alcohol, and some other aqueous cleaners). The LC[50] for nPB is 67 milligrams per liter (mg/l), which is greater and thus less toxic than an LC[50] of 10 mg/l, one of EPA's criteria for listing under the Toxics Release Inventory (US EPA, 1992; ICF, 2004a). Based on its relatively low bioconcentration factor and log K[ow] value (logarithm of the octanol-water partition coefficient), nPB is not prone to bioaccumulation. Table 5 summarizes information on environmental impacts of nPB; trans-1,2-dichloroethylene, a commonly-used solvent in blends for aerosol solvents, precision cleaning, and electronics cleaning; acetone, a commonly-used carrier solvent in adhesives; trichloroethylene, a solvent used for metals, electronics, and precision cleaning that could potentially be used in aerosol or adhesive end-uses; and methyl chloroform, an ODS that nPB would replace. **[*30175]**

Table 5.--Ecosystem and Other Environmental Properties of n PB and Other Solvents

Property	Description of environmental property	Value for nPB	Value for trans-1,2-dichloro-ethylene
K[oc], organic-carbon partition coefficient	Degree to which a substance tends to stick to soil or move in soil. Lower values (< 300) * indicate great soil mobility; values of 300 to 500 indicate moderate mobility in soil	330 (Source: ICF, 2004a)	32 to 49 (Source: ATSDR, 1996)
Break down in water	Mechanism and speed with which a compound breaks down in the environment. (Hydrolysis half-life	Hydrolysis is significant. Hydrolysis half-life of 26 days	Photolytic decomposition, dechlorination and biodegradation

Table 5.--Ecosystem and Other Environmental Properties of n PB and Other Solvents

Property	Description of environmental property	Value for nPB	Value for trans-1,2-dichloro-ethylene
	values > 25 weeks * are of concern.)	(Source: ICF, 2004a)	are significant; hydrolysis not significant (Source: ATSDR, 1996)
Volatilization half-life from surface waters	Tendency to volatilize and pass from water into the air	3.4 hours-4.4 days (Source: ICF, 2004a)	3 to 6.2 hours (Source: ATSDR, 1996)
LC[50] (96 hours) for fathead minnows	Concentration at which 50% of animals die from toxicity after exposure for 4 days	67 mg/L (Source: Geiger, 1988)	108 mg/L (Source: U.S. EPA, 1980)
log K[ow]	Logarithm of the octanol/water partition coefficient, a measure of tendency to accumulate in fat. Log K[ow] values >3 <; *> indicate high tendency to accumulate	2.10 (Source: ICF, 2004a)	-0.48 (Source: LaGrega et al., 2001, p. 1119)
Bioconcentra-tion factor	High factors (>1000) * indicate strong tendency for fish to absorb the chemical from water into body tissues	23 (Source: HSDB, 2004)	5 to 23 (Source: ATSDR, 1996)

Table 5.--Ecosystem and Other Environmental Properties of n PB and Other Solvents

Property	Value for acetone	Value for trichloroethylene	Value for methyl chloroform
K[oc], organic-carbon partition coefficient	5.4 (Source: ATSDR, 1994)	106 to 460 (Source: ATSDR, 1997)	152 (Source: U.S. EPA, 1994a).

Table 5.--Ecosystem and Other Environmental Properties of n PB and Other Solvents

Property	Value for acetone	Value for trichloroethylene	Value for methyl chloroform
Break down in water	Biodegradation is most significant form of breakdown (Source: ATSDR, 1994)	Volatilization and biodegradation most significant, with hydrolysis relatively insignificant. Hydrolysis half-life of 10.7 to 30 months (Source: ATSDR, 1997)	Volatilization most significant; biodegradation and hydrolysis also occur (Source: ATSDR, 2004).
Volatilization half-life from surface waters	7.8 to 18 hours (Source: ATSDR, 1994)	3.4 hours to 18 days (Source: ATSDR, 1997)	Hours to weeks (Source: U.S. EPA, 1994a).
LC[50] (96 hours) for fathead minnows	7280 to 8120 mg/L (Source: Fisher Scientific, 2001)	40.7 to 66.8 mg/L (Source: NPS, 1997)	52.8 to 105 mg/L (Source: U.S. EPA, 1994a).
log K[ow]	-0.24 (Source: LaGrega et al., 2001, p. 1117)	2.38 (Source: LaGrega et al., 2001, p. 1127)	2.50 (Source: LaGrega et al., 2001, p. 1127).
Bioconcentration factor	<1 (Source: ATSDR, 1994)	10 to 100 (Source: ATSDR, 1997)	<9 (Source: U.S. EPA, 1994a).

*Criteria from EDSTAC, 1998.

nPB is not currently regulated as a hazardous air pollutant and is not listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA). nPB is not required to be reported as part of the Toxic Release Inventory under Title III of the Superfund Amendments and Reauthorization Act. Despite this, large amounts of nPB might be harmful if disposed of in water. We recommend that users dispose of nPB as they would dispose of any spent halogenated solvent (F001 waste under RCRA). Users should not dump nPB into water, and should dispose of it by incineration. We conclude that nPB does not pose a significantly greater risk to the environment than other available alternatives, and that the use of nPB within the U.S. should not be prohibited under the SNAP program on the basis of its environmental impacts.

D. Flammability and Fire Safety

A number of commenters on the June 2003 proposal provided additional information on the flammability of nPB using standard test methods for determining flash point, such as the American Society for Testing and Materials (ASTM) D 92 open cup, ASTM D56 Tag closed cup, and ASTM D93 Pensky-Martens closed cup methods (BSOC, 2000; Miller, 2003; Morford, 2003a, 2003b, and 2003c; **[*30176]** Shubkin, 2003; Weiss Cohen, 2003). We agree with the commenters that by these standard test methods, nPB displayed no flash point. Thus under standard test conditions, nPB is not flammable, and it should not be flammable under normal use conditions. With its low potential for flammability, nPB is comparable to chlorinated solvents, HCFCs, HFEs, HFC-245fa, HFC-4310mee, and aqueous cleaners, and is less flammable than many

acceptable substitutes, such as ketones, alcohols, terpenes, and hydrocarbons. nPB exhibits lower and upper flammability limits of approximately 3% to 8% (BSOC, 2000). A number of other solvents that are typically considered to be non-flammable also have flammability limits (for example, methylene chloride, HCFC-141b, and methyl chloroform). If the concentration of vapor of such a solvent falls between the upper and lower flammability limits, it could catch fire in presence of a flame. Such a situation is unusual, but users should take appropriate precautions in cases where the concentration of vapor could fall between the flammability limits.

E. Health Impacts and Exposure

In evaluating potential human health impacts of nPB used as a substitute for ozone-depleting substances, EPA considered impacts on both exposed workers and on the general population. Using the same approach finalized in the original SNAP rulemaking, EPA evaluated the available toxicity data using EPA guidelines to develop health-based criteria to characterize human health risks (US EPA, 1994b. Inhalation Reference Concentration Guidelines; U.S. EPA, 1991. Guidelines for Developmental Toxicity Risk Assessment; U.S. EPA, 1995a. Benchmark Dose guidelines; U.S. EPA, 1996. Guidelines for Reproductive Toxicity Risk Assessment).

To assess human health risks, EPA followed the four basic steps of risk assessment outlined by the National Academy of Sciences: hazard identification, dose-response relationship, exposure assessment, and risk characterization (NAS, 1983). First, EPA examined available studies on nPB's effects. Second, EPA considered the acceptable exposure levels for evaluating worker exposure and a community exposure guideline (CEG) for evaluating exposure to the general population based upon inhalation exposure. Third, EPA compared the acceptable exposure levels and CEG to available exposure data and projections of exposure levels to assess exposure, including new exposure data available since publication of the June 2003 NPRM. Finally, EPA decided whether there was sufficient evidence indicating that nPB could be used as safely as other alternatives available in a particular end use.

Authority To Set an Acceptable Exposure Limit

Two commenters on the June 2003 NPRM said that EPA has no jurisdiction to develop any acceptable exposure limit (AEL) designed to be applicable to a workplace environment and that only the Occupational Safety and Health Administration (OSHA) has that authority (Stelljes, 2003; Morford, 2003d). In contrast, another commenter said that EPA has the authority to set an AEL for nPB under section 612 of the Clean Air Act, has done so in the past for other chemicals (e.g., HFC-4310mee, HCFC-225ca/cb), and should require the AEL as a use condition (Risotto, 2003).

EPA believes it has the authority to calculate exposure limits for the workplace under section 612. Section 612(c) specifically states that

The Administrator shall issue regulations: providing that it shall be unlawful to replace any class I or class II substance with any substitute substance which the Administrator determines may present adverse effects to human health or the environment, where the Administrator has identified an alternative to such replacement that--

(1) reduces the overall risk to human health and the environment; and

(2) is currently or potentially available.

Thus, we must compare the risks to human health and the environment of a substitute to the risks associated with other substitutes that are currently or potentially available, as required by the Clean Air Act. In order to compare risks to human health, EPA performs quantitative risk assessments on different chemicals comparing exposure data and exposure limits, following the process described above by the National Academies of Science (NAS, 1983) and as described in the preamble to the original final SNAP rule (March 18, 1994; 59 FR 13066). Because most humans who are exposed to nPB are exposed in the workplace, the appropriate exposure data and exposure limits to protect human health must include workplace exposure data and acceptable exposure limits for the workplace. Because there is wide disparity in acceptable exposure limits for nPB developed by industry, ranging from 5 ppm to 100 ppm (Albemarle, 2003; Chemtura,

2006; Docket A-2001-07, item II-D-19; Enviro Tech International, 2006; Farr, 2003; Great Lakes Chemical Company, 2001), and because there is not a Permissible Exposure Limit for nPB set by the Occupational Safety and Health Administration, EPA believes it is appropriate to independently evaluate the human health risks associated with use of nPB in the workplace. Similarly, EPA has developed a community exposure guideline to assess the human health effects of nPB exposure to the general public.

Skin Notation

Several commenters on the June 2003 proposal stated that a skin notation for nPB is appropriate, while another commenter agreed with EPA's proposal that no skin notation was necessary (Smith, 2003; HESIS, 2003; Werner, 2003, Weiss Cohen, 2003). Rat studies indicate that dermal exposure to nPB results in neither appreciable absorption through the skin (RTI, 2005) nor systemic toxicity (Elf Atochem, 1995). Unlike methyl chloride and dichlorvos, which are absorbed through the skin and could contribute to systemic toxicity (ACGIH, 1991), EPA is not proposing to include a skin notation for nPB in the information provided to users associated with this rulemaking because of the relatively low level of absorption. The American Conference of Governmental Industrial Hygienists (ACGIH) provides no skin notation in its documentation for threshold limit values (TLVs) for several solvents, including nPB (ACGIH, 2005), methylene chloride, and perchloroethylene, and there is no evidence that absorption through the skin is greater for nPB than for the other halogenated compounds. Further, including a statement giving advice about how to reduce skin exposure in the "Further Information" column of listings is likely to be more informative to workers than a skin notation.

Given the possibility that some nPB can be absorbed through the skin in humans, and that the solvent can irritate the skin, EPA encourages users to wear protective clothing and flexible laminate gloves when using nPB and encourages vendors to include such precautions in their Material Safety Data Sheets (MSDSs). EPA requests comment on whether it would be useful, in lieu of a skin notation to add the following statement in the "further information" column of each end use where we find nPB acceptable with restrictions: "EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing, when using nPB."

EPA also considered the potential health effects of contamination of nPB formulations with isopropyl bromide **[*30177]** (iPB). n7 In the June 2003 proposed rule, we proposed as a use condition that nPB formulations contain no more than 0.05% iPB by weight. One commenter opposed the proposed use condition, stating that it places an undue legal burden on end users, rather than the manufacturers of raw materials, that it would not benefit worker safety, and that the nPB industry has worked to reduce iPB content below 0.05% (Morford, 2003e). We agree that industry has met this contamination limit for several years without regulation. Furthermore, EPA agrees that if users are exposed to nPB concentrations no higher than the highest potentially acceptable concentration (30 ppm), a worker's exposure to iPB will be sufficiently low to avoid adverse effects. Therefore, this proposed rule does not include a use condition limiting iPB content in nPB formulations.

n7 iPB is also referred to as 2-bromopropane, 2-propyl bromide, or 2-BP. Its CAS registry number is 75-26-3.

1. Workplace Risks

In the June 2003 NPRM, EPA proposed that an exposure limit of 25 ppm would be protective of a range of effects observed in animal and human studies, including reproductive and developmental toxicity, neurotoxicity, and hepatotoxicity. Reduction of sperm motility in rats, noted across multiple studies at relatively low exposures, was determined to be the most sensitive effect. The Agency derived an exposure limit of 18 ppm from a dose response relationship in male rat offspring ("F1 generation") whose parents were exposed to nPB from prior to mating through birth and weaning of the litters (WIL, 2001). We then proposed to adjust this value upwards to 25 ppm based on principles of risk management, consistent with one of the original "Guiding Principles" of the SNAP program (59 FR 13046, March 18, 1994). As we discussed in the June 2003 NPRM, EPA noted that adhesives users should be able to achieve an AEL of 25 ppm and that 25 ppm was between the level based on the most sensitive endpoint (sperm motility in the F1 offspring generation at 18 ppm) and the second most sensitive endpoint (sperm motility in the F0 parental generation at 30 ppm). Following SNAP program principles, we noted that "a slight adjustment of the AEL may be

warranted after applying judgment based on the available data and after considering alternative derivations" (69 FR 33295). Because the animals were exposed to nPB for some time periods that would not occur during actual occupational exposure, we stated further that "18 ppm is a reasonable but possibly conservative starting point, and that exposure to 25 ppm would not pose substantially greater risks, while still falling below an upper bound on the occupation[al] exposure limit."

Since the 2003 proposal, the Agency has reviewed both information available at the time of the 2003 NPRM related to the health risks associated with nPB use, as well as more recent case studies of nPB exposures and effects in the workplace, newly published toxicological studies, comments to the June 2003 NPRM, including new risk assessments on nPB, and a new threshold limit value (TLV) issued by ACGIH.

OSHA has not developed a permissible exposure limit (PEL) for nPB that EPA could use to evaluate toxicity risks from workplace exposure. The ACGIH, an independent organization with expertise in industrial hygiene and toxicology, has developed a final workplace exposure limit of 10 ppm (ACGIH, 2005); however, as discussed below, EPA has concerns about the documentation and basis of ACGIH's derivation.

The Agency reconsidered which exposure levels are likely to protect against various health effects, based on review of all available information. We summarize benchmark dose data for a number of endpoints found in these analyses in Table 6 below. We examined these data to assess the acceptability of nPB use in the aerosol solvent, adhesive and coatings end uses reviewed in this proposed rule. These data indicate that, once uncertainty factors are applied consistent with EPA guidelines, the lowest levels for acceptable exposures would be derived for reproductive effects. n8 The data indicate that levels sufficient to protect against male reproductive effects (e.g., reduced sperm motility) would be in a range from 18 to 30 ppm, n9 in the range of 17 to 22 ppm to protect against female reproductive effects (e.g., number and length of estrous cycles), and at approximately 20 ppm for effects related to reproductive success (live litter size).

n8 By EPA guidelines, we would apply an uncertainty factor of -10, or approximately 3, for differences between species for all health effects. We would also apply an uncertainty factor of [radical] 10 (3) for variability within the working population for reproductive and developmental effects, because, among other reasons, these conditions would not necessarily screen out an individual from being able to work, unlike for liver or nervous system effects. Therefore, for reproductive and developmental effects, we use a composite uncertainty factor of 10. See further discussion of uncertainty factors in section V.C. below.

n9 Based on WIL, 2001, as analyzed in ICF, 2002. The equivalent values based upon Stelljes and Wood's (2004) analysis of WIL, 2001 would be slightly lower, from 16 to 28 ppm.

Table 6.--Summary of Endpoints Using Benchmark Response Modeling

Endpoint fna	Study	Benchmark dose lowerbound (BMDL) fnb (ppm)	Human equivalent concentration (HEC) fnc (ppm)
Liver Effects fnd			
Liver vacuolation in males (F[1] offspring generation)	WIL, 2001 as analyzed in ICF, 2002	110	116
Liver vacuolation in males (F[0] parent generation)	WIL, 2001 as analyzed in ICF, 2002	143	150
Liver vacuolation	ClinTrials, 1997b as analyzed in ICF, 2002 and Stelljes &	226	170

Table 6.--Summary of Endpoints Using Benchmark Response Modeling

Endpoint fna	Study	Benchmark dose lowerbound (BMDL) fnb (ppm)	Human equivalent concentration (HEC) fnc (ppm)
	Wood, 2004		
Reproductive Effects--Male			
Sperm motility (F[1] offspring generation)	WIL, 2001 as analyzed in ICF, 2002 WIL, 2001 as analyzed in Stelljes & Wood, 2004	169 156	177 164
Sperm motility (F[0] parent generation)	WIL, 2001 as analyzed in ICF, 2002 WIL, 2001 as analyzed in Stelljes & Wood, 2004	282 263	296 276
Prostate weight (F[0] parent generation)	WIL, 2001 as analyzed in TERA, 2004	190	200
Sperm count	Ichihara et al., 2000b as analyzed in Stelljes & Wood, 2004	232	325
Sperm deformities (F[0] parent generation)	WIL, 2001 as analyzed in Stelljes & Wood, 2004	296	311
Reproductive Effects--Female			
Number of estrus cycles during a 3 week period (F[0] parent generation)	WIL, 2001 as analyzed in ICF, 2006 WIL, 2001 as analyzed in ICF, 2006	162 208	170 218
Estrous cycle length (F[1] offspring generation) fnd	WIL, 2001 as analyzed in TERA, 2004	400	420
Estrous cycle	WIL, 2001 as	210	220

Table 6.--Summary of Endpoints Using Benchmark Response Modeling

Endpoint fna	Study	Benchmark dose lowerbound (BMDL) fnb (ppm)	Human equivalent concentration (HEC) fnc (ppm)
length (F[0] parent generation) fne	analyzed in TERA, 2004		
No estrous cycle incidence (F[1] offspring generation)	WIL, 2001 as analyzed in TERA, 2004	180	189
No estrous cycle incidence (F[0] parent generation)	WIL, 2001 as analyzed in TERA, 2004	480	504
Reproductive Effects--Reproductive Success			
Decreased live litter size (F[1] offspring generation)	WIL, 2001 as analyzed in TERA, 2004	190	200
Decreased live litter size (F[2] offspring generation)	WIL, 2001 as analyzed in TERA, 2004	170	179
Pup weight gain, post-natal days 21 to 28 (F[1] offspring generation)	WIL, 2001 as analyzed in TERA, 2004	180	189
Developmental Effects			
Fetal body weight	WIL, 2001 as analyzed in TERA, 2004	310	326
Fetal body weight	WIL, 2001 as analyzed in CERHR, 2002a	305	320
Nervous System Effects			
Hindlimb strength	Ichihara et al, 2000a as analyzed in Stelljes and	214	300

Table 6.--Summary of Endpoints Using Benchmark Response Modeling

Endpoint fna	Study	Benchmark dose lowerbound (BMDL) fnb (ppm)	Human equivalent concentration (HEC) fnc (ppm)
	Wood, 2004		

fna Unless explicitly stated, data are from a parental generation. Of the studies analyzed, only the WIL, 2001 study has multiple generations to be analyzed.

fnb The benchmark response value represents a specified level of excess risk above a control response.

fnc When considering workplace exposures, the human equivalent concentration is the BMDL, adjusted to apply to a 40-hour work week in which workers are exposed for 8 hours a day for five days per week. Animals in the WIL, 2001 study were exposed for 6 hours a day, 7 days a week. Animals in the Ichihara, 2000a and 2000b studies were exposed for 8 hours a day, 7 days a week. Animals in the ClinTrials, 1997b study were exposed for 6 hours a day, 5 days a week.

fnd After applying an uncertainty factor of 3 for animal to human extrapolation, acceptable levels of exposure to protect against liver effects would be in the range of 39 to 57 ppm.

fne Omits data from those animals that have stopped estrous cycling altogether (TERA, 2004).

2. General Population Risks

EPA used a community exposure guideline of 1 ppm to assess potential risks to the general population living near a facility using nPB (see section V.E below). Of the end uses covered in this rule, use of nPB-based adhesives would result in the highest exposure levels, and so, we first examined general population exposure from adhesives. ICF Consulting modeled inhalation exposure to nPB to people living near a plant using nPB-based adhesives in several scenarios using the Agency's SCREEN3 model (US EPA, 1995b). Based on this modeling, EPA found that the exposure to individuals in the general population was below the community exposure guideline. The analysis indicates that nPB is no greater a hazard to the general population than other acceptable solvents under the SNAP program. For further discussion, see the risk screen for nPB (ICF, 2006a).

Representatives from a state environmental agency and from a potential user of nPB have asked EPA whether we had developed a reference concentration (RfC). We clarify that the community exposure guideline is a value developed by the SNAP program for our risk assessment of nPB following EPA's RfC Guidelines. However, it is not a formal RfC developed by EPA's National Center for Environmental Assessment and is not in IRIS. At this time, EPA does not have plans to issue an official RfC for nPB.

V. How did EPA assess impacts on human health?

A. Newly Available Exposure Data

Since publication of the June 2003 NPRM, EPA has received additional information on exposure levels in each end use discussed in this proposal.

In the adhesives end use, we considered new exposure modeling based on information from site visits to facilities using spray adhesives (ICF, 2006a). These data predicted that:

. At average rates of ventilation and adhesive application, average workplace exposures would be approximately 60 ppm.

. Average adhesive application rates and poor ventilation rates resulted in average exposures of approximately 250 ppm.

. High (90th percentile) adhesive application rates and average ventilation rates resulted in average exposures of approximately 600 ppm.

. In the worst case scenario with high adhesive application rates and poor ventilation, average workplace exposures would be as high as 2530 ppm.

We compared the modeled data in the four exposure scenarios to measured exposure data in three health hazard evaluations by the National Institute for Occupational Safety and Health (NIOSH) (NIOSH 2002a, 2002b, 2003a). **[*30179]** Our understanding is that North Carolina OSHA received complaints from workers and requested that NIOSH evaluate health hazards at these three facilities. NIOSH found average exposure levels of 68 ppm, 116 ppm, 127 ppm, and 195 ppm for sprayers actively using the adhesive prior to installation of state-of-the-art ventilation systems (NIOSH 2002a, 2002b, 2003a). The plant with an average exposure level of 68 ppm for sprayers (9 samples) had an average exposure level comparable to the average concentration of 60 ppm in the modeling scenario with average adhesive rates and average ventilation levels. The other plants with average exposure levels of 116 to 127 ppm (20 samples), and of 195 ppm (36 samples) for sprayers had exposure levels between the average modeled exposure for a facility with average adhesive application rates and average ventilation (60 ppm) and the average modeled exposure for a facility with average adhesive application rates and poor ventilation (250 ppm). Based on this comparison, EPA believes the modeled exposure levels are a reasonable predictor of actual exposure based on current industry practice in the adhesive end use.

In the aerosol solvent end use, we received a study on workplace exposure levels of nPB-based aerosols from a commenter (Linnell, 2003). This study was performed to simulate typical exposure levels in a number of situations where nPB might be used in the workplace while using different types of ventilation equipment, rather than using data from current industry users of nPB-based aerosols in their actual manufacturing or maintenance processes. As discussed below in section VI.A., we are concerned that the exposure data and ventilation levels in this study may not be representative of use of nPB-based aerosols in industry. Personal breathing zone samples taken from the collars of workers showed 8-hour time-weighted average (TWA) exposures of 5.5, 13, and 32 ppm for workers using 310 g of nPB from a spray can n10 (Linnell, 2003). The two higher exposure levels occurred in the absence of any local or regional ventilation; the use of both local and regional ventilation equipment with ventilation levels around 1900 ft<3> /min was associated with the lowest exposure level. Short-term exposures of 370, 1,100 and 2,100 ppm taken from a room with regional ventilation at 640 cubic feet per minute (cfm), when averaged over an 8-hour period, resulted in exposures of 12, 34, and 66 ppm (Linnell, 2003). EPA considers the highest of these 8-hour values, 66 ppm, not to be representative of worker exposure from inhalation because the measurement was taken from the worker's wrist, rather than from his breathing zone. Another short-term exposure value of 190 ppm, taken from a vented booth with local ventilation at 472 cfm, in addition to the regional ventilation of 640 cfm, resulted in an 8-hour exposure of 6 ppm. Similar measurements were made in another study we considered in developing the June 2003 NPRM: Eight hour (8-hr) TWA exposures of 11.3, 15.1, 17.0, and 30.2 ppm with regional ventilation of 300 cubic feet per minute from a fan for the entire room (Confidential submission, 1998).

n10 Unlike samples measured directly in the breathing zone, area samples measured in the study are not considered representative of actual exposure and are not discussed here. Short-term measurements taken over 15 minutes from personal samplers, although in some cases extremely high, are not discussed in detail here because available toxicity information does not indicate need for a short-term exposure limit for nPB in addition to the 8-hr TWA limit (ACGIH, 2005; ERG, 2004). Additional information on these other samples is in the occupational exposure assessment for aerosols in the risk screen for nPB (ICF, 2006a).

Another commenter submitted information on aerosol exposures for a number of other available alternative aerosols (Werner, 2003). While these data do not include nPB, based on the properties of aerosol solvents, we believe it is reasonable to compare concentrations of these different chemicals to potential nPB exposures. The study compared concentrations of eight different chemicals that are acceptable under the SNAP program in aerosol formulations: HFE-7100, HFE-7200, trans-1,2-dichloroethylene, HCFC-225ca and -225cb, acetone, pentane, and HFC-134a. In this study, with ventilation of only 48 cfm, 8-hr TWA exposure

from the different chemicals varied from 35.5 ppm to 194.0 ppm, n11 below the recommended exposure levels for these particular chemicals (ICF, 2006a) but above the range of exposure levels that EPA would consider acceptable for nPB.

n11 These measurements can be converted to estimates of nPB exposure by multiplying the measured concentration of the alternate chemical by the molecular weight of the same alternate chemical and dividing this by the molecular weight of nPB, 123. After performing this calculation, the equivalent exposure levels for nPB vary from 29.5 ppm to 394.4 ppm.

In addition, we considered new information from modeling of nPB exposures (ICF, 2006a). The modeling examined exposure levels that would be expected at ventilation levels of 450 cfm, 625 cfm, and 1350 ppm, considering the molecular weight of the compound and the composition of different aerosol blends. EPA's SNAP program has previously used these same levels to calculate potential aerosol exposures, based upon exposure levels expected during benchtop cleaning. In a space with an air exchange rate of 450 ft[3] /minute or less, n12 EPA's modeling predicts 8-hour average exposure of approximately 16 to 17 ppm if a user sprays 450 g of nPB (approximately 1 lb), n13 and corresponding higher exposure values at higher spray rates (e.g., 33 ppm if the amount of nPB sprayed is 900 g) (ICF, 2006a). Exposure values were predicted to be lower at higher ventilation rates.

n12 This corresponds roughly to a regional or room fan at low levels or natural air currents in an open area. Confined areas would have even lower air exchange rates with higher exposure levels.

n13 We consider use of 1000 g/day to be the high end of typical use, based on the setup of one of the exposure studies (Confidential Submission, 1998). The typical aerosol solvent user in the electronics industry uses a can per day (Williams, 2005). This is comparable to or slightly less than the spray rate assumed in the modeling.

Since the June 2003 NPRM, EPA received a new submission for nPB in coatings (Lake City Army Ammunition Plant, 2003). The Lake City Army Ammunition Plant provided data on workplace exposure to nPB (Lake City Army Ammunition Plant, 2004). The mean exposure at this facility was 3.7 ppm. Out of 31 samples taken, 25 (approximately 80%) were below 5 ppm. Only one of 31 samples had an exposure level above 10 ppm, and that exposure value was approximately 21 ppm.

B. Newly Available Data on Health Effects

Since publication of the June 2003 NPRM, EPA has examined additional occupational (Table 7) and animal (Table 8) studies that have become available: **[*30180]**

Table 7.--Recent Studies on n PB Occupational Exposure

Case Study	Sample size/population	Exposure data
Beck and Caravati, 2003	6 foam cushion factory workers (gluers)	Exposure during 30-40 hr/wk for a 3-month period. Exposure measured in one day was a mean of 130 ppm (range, 91-176 ppm)
Majersik et al., 2004; Majersik et al., 2005 *	6 foam cushion factory workers (gluers)	5-8 hr/day for at least 2 years with mean air concentration of 130 ppm on last day of study. Measurements taken over 9 hours (equivalent to 92-127 ppm with mean of 108 ppm for an 8-hour TWA)
Ichihara et al., 2004a	37 chemical plant workers (24 males and 13 females)	12 hour shifts over 2-day period, mean

Table 7.--Recent Studies on n PB Occupational Exposure

Case Study	Sample size/population	Exposure data
Ichihara et al., 2004b	27 female chemical plant workers (23 age matched with 23 females from a beer factory control group)	concentration of 82 ppm (range, 0-170 ppm) 1-day exposure period, range of exposure, 0.34-49 ppm
Nemhauser, 2005 * workers (gluers) in North exposed to mean air	Foam cushion factory Carolina	In 1999 study, 16 workers concentration of 116 ppm, and 12 sprayers exposed to mean concentration of 108 ppm with range of 58 to 254 ppm. In 2001 study, 13 workers exposed to nPB mean air concentration of 46 ppm and 12 sprayers were exposed to mean concentration of 101 ppm, with range of 38 to 281 ppm
NIOSH, 2003a	16 workers in 1999 evaluation; 13 workers in 2001 follow-up evaluation	1999 Initial Site Visit: Geometric mean nPB concentration (from personal samples), 81.2 (range, 18-254 ppm); 2001 follow-up: Geometric mean, 81.2 ppm (range, 7-281 ppm)
Raymond and Ford, 2005 *	4 foam cushion factory workers (gluers) in North Carolina	Exposure study conducted 9 months after index patient became ill indicated workers exposed to mean nPB air concentration of 116 ppm. 4 workers exposed for 2-3 weeks before initial symptoms detected
Toraason et al., 2006	41 and 22 foam cushion factory workers (gluers) at 2 facilities	1-3 days up to 8 hrs per day, with concentrations of 0.2-271 ppm at facility A, 4-27 ppm at facility B

Table 7.--Recent Studies on n
PB Occupational Exposure

Case Study	Observations	Remarks
Beck and Caravati, 2003	Lower leg weakness accompanied by pain and difficulty with standing and walking, numbness of legs and feet, hyperreflexia and hypertonicity of lower extremities, dizziness and shortness of breath, and peripheral neurotoxicity. Measured serum bromide levels were elevated, range 44-170 mg/dL	Small sample size studied. Possible interference or synergistic effects from other adhesive ingredients (1,2-epoxybutane and styrene-butadiene).
Majersik et al., 2004; Majersik et al., 2005 *	Subacute onset of lower extremity pain, difficulty walking, and high serum bromide levels in blood. Neurotoxic symptoms persisted for at least 2 years after exposure ended	Follow-up to Beck and Caravati (2003). Chronic nPB exposure associated with incapacitating neurotoxic syndrome. Initial report from Utah OSHA indicated erroneously that workers were not spraying while measurements were taken. In fact, adhesives were being sprayed and fans were being used only for portions of the day that measurements were taken, making measurements likely to be representative of conditions during the past several months at the plant.
Ichihara et al., 2004a	Mucosal irritation (nose, throat), headache, dizziness, constipation, intoxication, and feeling light-headed or heavy-headed. Four female workers complained of disruption or cessation of menstruation. No severe chronic symptoms of neurological damage at less than 170 ppm. Several workers had hemoglobin and hematocrit values outside of the normal range and were	Inadequate exposure characterization and exposure to other potential toxicants, small sample size, and no appropriate control group. Healthy worker effect possible, where more sensitive workers left the factory between 1996 and 1999.

Table 7.--Recent Studies on n PB Occupational Exposure

Case Study	Observations	Remarks
	diagnosed with mild anemia; most of these cases also showed signs of iron deficiency	
Ichihara et al., 2004b	Responses indicated anxiety, fatigue, confusion, tension, and depression. Changes in menstrual status but not statistically significant. Effects on peripheral and central nervous system--diminished vibration sensation of the foot; significantly longer distal latency in the tibial nerve; decreased values in sensory nerve conduction velocity in the sural nerve; and lower scores on memory and perceptual tests. No comparable effects seen in control group	No long-term exposure measurements, small sample size; lack of controls for age, height, and body-weight. Low B vitamin levels in normal range in some workers but researchers concluded this did not cause observed neurological effects. Additionally, the study did not indicate any significant differences in the prevalence of menstrual cycle abnormalities.
Nemhauser, 2005 * and dose-dependentstudied with moderate	Higher exposure to nPB	Small sample sizes
	relationship among those who reported anxiety, headache, and ataxia. No reproductive abnormalities reported in medical survey for men or women. Semen analysis found no differences between exposed and unexposed workers	worker participation. Healthy worker effect likely occurred: Those that had most significant health effects had already removed themselves from workplace by the time of the study. No arsenic found at the plant. Neurotoxic effects caused by nPB. See related Health Hazard Evaluation (HHE): NIOSH, 2003a.
NIOSH, 2003a	Most workers exposed to nPB levels > 25 ppm. Exposure concentrations lower in 2001 than 1999, but difference not statistically significant. Headache, anxiety, feeling drunk	Arsenic was not attributed to occupational exposure. The National Institute for Occupational Safety and Health (NIOSH) stated that neurological symptoms may have been

Table 7.--Recent Studies on n PB Occupational Exposure

Case Study	Observations	Remarks
	associated with nPB exposure. Hematological endpoints unaffected in exposed group. No correlation of nPB exposure with sperm or semen indices or with neurological abnormalities	related to excess exposure to nPB, but that no other effects could conclusively be related to nPB exposure.
Raymond and Ford, 2005 *	Dizziness, numbness, ocular symptoms, lower extremity weakness and unsteady gait, weakness, hypesthesia, and ataxic gait in all four workers. Symptoms decreased over time but after six years, at least one worker re-exposed twice at other furniture plants; one or more still suffer from ataxia	Small sample size, possible confounding effect from arsenic.
Toraason et al., 2006	No statistically significant differences in DNA damage with worker's nPB exposure. In vitro results showed nPB increased DNA damage	Authors find limited evidence that nPB poses a "small risk" for DNA damage.

* Presentation at North American Congress of Clinical Toxicology on September 14, 2005.

Table 8.--Recent Animal Studies of n PB Effects

Citation	Population/sample size	Exposure
Fueta et al., 2002	24 male Wistar rats (12 control, 12 exposed)	6 hr/day, 5 day/wk for 8 weeks at 700 ppm
Fueta et al., 2004	58 male Wistar rats (29 experimental and 29 in control group)	6 hr/day, 5 day/wk for 4 to 8 weeks, 700 ppm
Furuhashi et al., 2006	80 Wistar rats (pups and their dams)	(1) 8 hr/day (4 hr, followed by 2.5-hr rest period, followed by 4 hr exposure), 7 day/wk during gestation and nursing at 0, 100, 400, 800 ppm in first experiment (2) Dams exposed (800 ppm) during gestation (Group A), offspring not exposed during nursing.

Table 8.--Recent Animal Studies of n PB Effects

Citation	Population/sample size	Exposure
		Offspring of Group (B) of unexposed dams were nursed by exposed dams. Offspring in control groups C and D not exposed
Honma et al., 2003	Fisher 344 male rats	8 hr/day, 7day/wk for three weeks exposed to 0, 10, 50, 200 or 1000 ppm (5 rats/dosage and 5 different tests)
Ishidao et al., 2002	30 male Wistar rats	6 hr/day, 5 day/wk with test groups (10/dose) exposed to 700 ppm for 4 and 12 weeks and 1500 ppm for 3 and 4 weeks
NTP, 2003	Female and male B6C3F1 mice and Fischer 344 rats	0, 62.5, 125, 250, 500 (rats and mice), 1000 (rats) ppm for 90 days
RTI, 2005/ Garner et al., 2006	Female and male B6C3F1mice and Fisher 344N rats, four to six animals in each test trial	Exposure via several injection routes (intraperitoneal, intravenous, cannuliz-ation), inhalation, and dermal. Injection conducted via bolus dosing at 5, 20, or 100 mg/kg body weight. Inhalation concentrations of 70, 240, 800, and 2700 ppm administered in a single acute exposure. A dose of 96 mg/kg was applied to a shaved area on the backs of six male rats with a non-occlusive charcoal filter covering (that is, one that does not prevent evaporation)
Sohn et al., 2002	40 male and 40 female Sprague-Dawley rats	6 hr/day, 5 day/wk for 13 weeks, test groups (10/sex/dose) were exposed to 0, 200, 500 or 1250 ppm
Stump, 2005 *	125 female/125 male rats in first generation and 100 female/100 male rats in offspring generation	Both test groups of 25 male rats/ 25 female rats exposed to 0, 100, 200, 250, 500 and 750 ppm nPB for 10 weeks
Wang et al., 2003	36 male Wistar rats	8 hr/day, 5 day/wk for 12 weeks, test groups (9

Table 8.--Recent Animal Studies of n PB Effects

Citation	Population/sample size	Exposure
		rats) were exposed to 0, 200, 400 or 800 ppm
Yamada et al., 2003	40 female Wistar rats	8 hr/day, 7 day/wk with test groups (9/dose) exposed to 0, 200, 400, or 800 ppm for 12 weeks

Table 8.--Recent Animal Studies of n PB Effects

Citation	Observations	Comments
Fueta et al., 2002	No apparent morphological defects in the brain	Only one exposure concentration was used (which is higher than the level already associated with other toxic effects in rodents [400 ppm]) and a shorter exposure duration (8 weeks) was used than the other subchronic studies that have shown effects (13 weeks).
Fueta et al., 2004	No apparent morphological defects in the brain. Chronic inhalation changes brain enzyme levels and electrical activity that is reversible after exposure	Unclear how nPB and/or its metabolites directly act on receptors or channels in the brain.
Furuhashi et al., 2006	(1) At 800 ppm: most rat offspring died within 2 days of birth or in utero;. body weights of dams significantly lower, organ weights of offspring significantly lower after weaning at 800 ppm in males, and 800 and 400 ppm in females. Most sperm and estrous indicators did not differ among the groups, although the rate of sperm arrival to the cauda epididymis was significantly lower in the 400 ppm group.	Authors concluded that exposure to nPB during pregnancy and lactation adversely affects growth and survival of offspring. Low numbers of offspring in 400- and 800-ppm exposure groups prevent statistical testing EPA comments: Study design inconsistent with guidelines for developmental studies, so comparisons to previous studies are difficult. The mechanism for the adverse effects observed

Table 8.--Recent Animal Studies of n PB Effects

Citation	Observations	Comments
	Inconsistent or no changes in biochemical indicators (2) Second experiment No difference in body weights and pregnancy endpoints between exposed (800 ppm) and unexposed dams. Live offspring at birth, survival rates, body weights, significantly decreased, number of dead offspring, significantly increased in 800-ppm groups	is not known (e.g., indirect exposure through milk, changes in nursing behavior, changes in milk production, exposure in utero, changes in the intrauterine environment)
Honma et al., 2003	3 week exposure to greater than 50 ppm temporarily increased locomotor activity and ambulatory and rearing behaviors in male rats	Neurological effects shown to be transient and reversible at >/= 200 ppm (Ichihara et al., 2000) or absent after 28 days of exposure at concentrations >/= 400 ppm (ClinTrials, 1997a) or after 90 days of exposure at concentrations up to 600 ppm (ClinTrials, 1997b) in other studies. Human studies are limited by co-exposures and poor estimates of exposure concentrations. Thus, EPA is not using this endpoint as the basis of an AEL.
Ishidao et al., 2002	nPB is metabolized rapidly in the rat following exposures to nPB at concentrations >/= 700 ppm for at least 3 weeks	Exposure levels are higher than in some other studies and are much higher than concentrations seen in the workplace. nPB metabolism appears to be different following multiple exposures as compared to acute exposures (see RTI, 2005; ICF, 2006b).
NTP, 2003	Early mortality in mice at 500 ppm accompanied by liver and lung cell degeneration and	Unpublished study. Conclusions drawn from a review of raw data from the National Toxicology

Table 8.--Recent Animal Studies of n PB Effects

Citation	Observations	Comments
	cytoplasmic vacuolization. Cytoplasmic vacuolization also in rat liver cells >/= 250 ppm (males) and >/= 500 ppm (females), with increased severity at higher doses. No adverse central nervous system (CNS) effects or histopathology reported	Program (NTP) Web site. In general, the severity of effects (in non-reproductive organs) is slightly higher at lower concentrations in male rats than in females.
RTI, 2005/ Garner et al., 2006	nPB cleared by mice after 48 hours as follows: 45% as volatiles in the breath, 28% as CO[2] in the breath, 26% in urine, <3% in feces, and 2% retained in the body. Distribution was similar in male rats, although amounts in urine and volatiles in breath were higher in mice. At higher doses, the amount of nPB excreted in urine and as CO[2] decreased, with a much greater change in rats compared to mice . After pretreatment with a cytochrome P450 inhibitor, a decrease in nPB cleared as CO[2] (80%) and urine (40%); pretreatment with a glutathione inhibitor reduced nPB cleared as CO[2] by 10% and urine by 4% . The Vmax, a measure of the maximum initial rate of an enzyme-catalysed reaction, is 0.227 for male rats, 0.143 for female rats, 0.329 for male mice and 0.234 for female mice. Half-lives were comparable between males and females at </= 800 ppm . For rats exposed to nPB through skin, 37% of	The study authors concluded that: . nPB administered via intraperitoneal injection or inhalation is eliminated mostly through the breath, with urine as a secondary path. . Metabolism of nPB appears to be primarily through cytochrome P450 enzymes (CYP2E1), particularly in mice; glutathione conjugation still plays an important role in rats. . At high concentrations, female rats may have a decreased capacity to metabolize nPB compared to male rats. . nPB decreases glutathione levels in the liver after a one-time exposure to nPB at concentrations as low as 70 ppm. . nPB is not appreciably absorbed ([approx.] 3-27%) in rats following dermal application. EPA agrees with these points, except we found that gender differences were only apparent in rats at very high concentrations (2700 ppm and greater). We also note that:

Table 8.--Recent Animal Studies of n PB Effects

Citation	Observations	Comments
	the dose was excreted in volatiles, 1.2 % in urine, 1.7% as CO[2], and 35.7% was on the applicators or in the skin washes. Only 0.32% remained in tissues. Airborne concentrations of nPB in the chamber were 4 to 10 ppm after dosing	. Inhalation tests were only one-time exposures at very high concentrations (240 to 2700 ppm), and thus, are not comparable to long-term dosing at the lower levels expected in the workplace. . Results of dermal testing are not conclusive because of potential for inhalation exposure.
Sohn et al., 2002	No effects on mortality, activity, weight gain, food consumption, urinalysis, or histological effects in the brains and spinal cords	The differences between the various studies may be due to variability in exposure methodology and achieved concentrations of nPB.
Stump, 2005 *	Decreased litter size at 250 and 500 ppm in both generations. Decreased fertility at 100 and 250 ppm in offspring generation Complete infertility at 750 ppm.	Reproductive effects seen in both rat sexes which is a strong signal of reproductive toxicity potential in humans. The author considers 100 ppm to be a lowest observed adverse effect level (LOAEL). This is a presentation of data from WIL, 2001.
Wang et al., 2003	Decrease in creatine kinase in the spinal cord (17% at >/= 200 ppm) and brain (15-28% at >/= 400 ppm) at 200, 400, and 800 ppm. No physical or behavioral changes observed	Small study size. No behavioral changes or physical symptoms were observed in the animals, so the toxicological relevance of the decrease in creatine kinase is questionable.
Yamada et al., 2003	All rats at 800 ppm became seriously ill after 7 weeks of exposure. Significant decrease in antral follicles at >/= 200 ppm, and a decrease in the number of female rats exhibiting regular estrous cycles in 400-ppm females during 7-9 weeks	Data suggest that nPB is affecting the maturation of ovarian follicles. A no observed adverse effect level (NOAEL) of 200 ppm is identified with a LOAEL of 400 ppm for the changes in estrus cycles.

Table 8.--Recent Animal Studies of n PB Effects

Citation	Observations	Comments
	of exposure and at 2-3 weeks at the 800-ppm dose	

* Presentation at North American Congress of Clinical Toxicology on September 14, 2005 **[*30183]**

. In general, the recent animal studies collectively show a range of effects associated with nPB exposure that are qualitatively consistent with previously published findings. (Exceptions to this are the negative results regarding central nervous system toxicity in the NTP (2003) study and the Sohn (2002) study on rats.) Some general conclusions we draw from the new studies include:

. Case reports of nPB exposure in the workplace indicate that severe, possibly irreversible, neurological effects may occur at sustained concentrations of approximately 100 ppm or greater (Beck and Caravati, 2003; Majersik *et al*, 2004; Majersik *et al.*, 2005; Ichihara *et al.*, 2002a; Miller, 2005; Raymond and Ford, 2005). In other cases, similar or higher concentrations up to 170 ppm caused less severe nervous system effects (Nemhauser, 2005; NIOSH, 2003a; Ichihara, 2004a). Some neurological effects occurred in workers at levels of less than 50 ppm (Ichihara *et al.*, 2004b). Because of design and methodological limitations, such as small numbers of subjects and limited exposure information, these studies do not provide a sufficient quantitative basis to derive an acceptable exposure limit.

. Data on female rats indicate that nPB affects the maturation of ovarian follicles and the ovarian cycle (Yamada *et al.*, 2003), consistent with previously reviewed data (WIL, 2001; Sekiguchi *et al.*, 2002).

. Some data on occupation exposure suggest that workers exposed to nPB may have experienced menstrual disorders (Ichihara *et al.*, 2002; Ichihara *et al.*, 2004b). However, the data are not statistically significant and are not sufficient to conclude that nPB exposure caused these female reproductive effects.

. Data on DNA damage in workers exposed to nPB was not statistically significant (Toraason *et al.*, 2006).

. Metabolic data on mice and rats indicate some species differences. Metabolism of nPB appears to be primarily through cytochrome P450 enzymes, particularly in mice; glutathione conjugation also plays a role, and a bigger role for rats than for mice (RTI, 2005).

. New data from toxicological studies on nervous system effects remain inconsistent and equivocal concerning the level at which nervous system effects occur (Fueta *et al.*, 2002; Fueta *et al.*, 2004; Honma *et al.*, 2003; Ishidao *et al.*, 2002, NTP, 2003; Sohn *et al.* 2002, Wang *et al.*, 2003).

A number of commenters on the June 2003 NPRM suggested that EPA should consider neurotoxicity as the endpoint in deriving an AEL for nPB (Linnell, 2003; Werner, 2003; Rusch and Bernhardt, 2003, Rusch, 2003). In particular, they requested that EPA consider the study conducted by Wang (2003) and epidemiological data on neurotoxic effects of nPB. As discussed above, the data on neurotoxic effects of nPB on workers are limited and are not sufficient to determine acceptable levels of exposure. In the study on rats by Wang *et. al.* (2003), measurements found a decrease in enzymes in the spinal cord and brain at 200, 400, and 800 ppm, but the animals displayed no physical or behavioral changes. Because of the lack of physical symptoms or behavioral changes, EPA does not believe that the decrease in enzyme levels in the central nervous system are toxicologically relevant. Other studies examining neurological effects of nPB showed those effects to be transient and reversible at and above 200 ppm (Ichihara *et al.*, 2000a). Exposures of 200 ppm and above for three weeks had no effect on memory, learning function, or coordination of limbs (Honma, 2003); the effect of spontaneous locomotor activity seen in this study at 50 ppm and above was not considered adverse by the authors. In other studies, neurological effects were absent after extended periods of exposure-after 28 days of exposure at concentrations > 400 ppm (ClinTrials, 1997a) and after 90 days of exposure at concentrations up to 600 ppm (ClinTrials, 1997b). Thus, although neurological effects have been associated with nPB exposure, the data are currently insufficient to quantify and determine acceptable exposure levels based on this endpoint.

One commenter on the June 2003 NPRM requested that EPA evaluate a study by Yamada *et al.* (2003), a study published just prior to the June 2003 NPRM. In response to the comment, EPA reexamined Yamada *et al.*, 2003 and re-evaluated the literature (Ichihara *et al.*, 1999, 2002, 2004a,b; Sekiguchi, 2002, Yamada *et al.*, 2003; WIL, 2001) to assess potential reproductive toxicity in females (ICF, 2006a, Att. A). A peer review of these effects is in the public docket (ICF, 2004b). Multiple benchmark analyses found a statistically significant decrease in the number of estrous cycles and increase in estrous cycle length associated with nPB exposure, consistent with other reproductive endpoints, namely reductions in sperm motility, decreased live litter size, and change in prostate weight (ICF, 2002a; ICF, 2006a; Stelljes and Wood, 2004; TERA, 2004).

Reproductive effects are seen in males, females, and offspring, and in different generations of the two-generation study (WIL, 2000). They also are consistent with results seen in one-generation reproductive studies, such as Ichihara *et al.* (2000b) and Yamada (2003). See Table 6 above in section IV.E.1. for a more complete list of the different health effects. EPA believes that the preponderance of the data indicate that exposure levels sufficient to protect against male reproductive effects (*e.g.*, reduced sperm motility) would be in a range from 18 to 30 ppm, in the range of 17 to 22 ppm to protect against female reproductive effects (*e.g.*, number and length of estrous cycles), and at approximately 20 ppm for effects related to reproductive success (live litter size). We have not determined what specific level within those ranges (an overall range of 17 to 30 ppm) is most appropriate for evaluating whether a substitute may be used safely and consider these exposure levels to be potentially acceptable. Therefore, we assessed the acceptability of nPB by considering whether it could be used safely in the three end-uses. For end-uses with likelihood of exposures above the range we are considering, while following typical industry practices, we are proposing an unacceptability determination. For end-uses that as their normal practice meet exposure levels below the range we are considering, we are proposing an acceptability determination. It is not necessary for 100% of exposure data for an end use to be above or below the range of 17 to 30 ppm in order to make a determination on the acceptability of an end use because there may be occasional cases that are not following common industry practices. Unusual events would not indicate the industry's likelihood of keeping exposures at safe levels, and thus, should not be the determining factor in our decision. Rather, we consider the overall likelihood that typical industry use would consistently result in acceptably low or unacceptably high exposures.

In the June 2003 NPRM, EPA used a BMDL of 169 ppm as a point of departure for developing an AEL. Some commenters stated that data from the F1 generation is inappropriate for calculating occupational exposure, citing statements from toxicologists, such as, "occupational exposure involves adults only." They also stated that EPA has not required this for other chemicals and that the resulting value is more conservative than what is normal and appropriate for industrial toxicology (Morford, 2003f, Ruckriegel, 2003). Others stated that sperm motility effects on the F1 generation are appropriate to consider (Risotto, 2003; Farr, 2003), particularly because of the **[*30184]** potential for *in utero* effects and because of the consistent presence of these reproductive effects in both generations and at multiple levels. EPA acknowledges that using data from the F1 offspring generation may be conservative because the pups in the F1 generation were exposed to nPB between weaning and sexual maturity (WIL, 2001). During occupational exposure, this period of exposure would not occur because children under age 16 are not allowed to work in industrial settings. However, EPA believes that because of the potential for *in utero* effects that would only be seen in the offspring generation, looking only at the F0 parental generation could underestimate the adverse health impacts of a chemical. Therefore, we believe it is appropriate to consider effects seen in both the F0 parental generation and the F1 offspring generation. Further, effects on sperm motility in the parental and offspring generations are seen at levels generally consistent with multiple reproductive effects seen in both generations and both sexes exposed to nPB, such as estrous cycle length, lack of estrous cycling, the number of estrous cycles in a given period of time, fertility indices, and the number of live pup births (TERA, 2004; ICF, 2006a; SLR International, 2001). Therefore, we believe that the available data indicate that in order to protect against adverse reproductive effects, an exposure level within the range of 17 to 30 ppm, would potentially be acceptable. We would reach the same proposed decisions of unacceptability based upon data from the F0 generation.

C. Evaluation of Acceptable Exposure Levels for the Workplace

To calculate acceptable exposure levels for nPB, EPA uses standard risk assessment methods delineated in Agency guidance (U.S. EPA, 1994b) in evaluating data, choosing a benchmark dose level or a

NOAEL, and making the adjustments and uncertainty factors prescribed to account for differences in the duration of exposure and in sensitivity between and within species.

Adjustment for Occupational Exposure Pattern

To account for differences between the exposure pattern used in the WIL study (6 hours per day for 7 days per week) when compared to a typical workweek of 8 hours per day and 5 days a week, a "human equivalent concentration" (HEC) is first calculated by adjusting the benchmark dose level:

(BMDL in ppm x 6 hours/8 hours) x 7 days/5 days = HEC (ppm)

HECs for the major health endpoints are shown in Table 6 above in section IV.E.1.

Uncertainty Factors

According to EPA risk assessment guidance for reference concentrations (RfC) (EPA 1994a), uncertainty factors of up to 10 may be applied to the HEC for each of the following conditions:

(1) Data from animal studies are used to estimate effects on humans;

(2) Data on healthy people or animals are adjusted to account for variations in sensitivity among members of the human population (inter-individual variability);

(3) Data from subchronic studies are used to provide estimates for chronic exposure;

(4) Studies that only provide a LOAEL rather than a NOAEL or benchmark dose; or

(5) An incomplete database of toxicity information exists for the chemical.

EPA believes that two uncertainty factors are appropriate for this database to account for that: (1) Physiological differences between humans and rats; and (2) variability within the working population. The rationale for the use of these two uncertainty factors is described below.

EPA RfC guidelines state that an uncertainty factor of 10 may be used for potential differences between study animals and humans. This factor of 10 consists in turn of two uncertainty factors of 3--the first to account for differences in pharmacodynamics n14 and the second to account for differences in pharmacokinetics n15 between the study of animal and humans. (The value of three is the square root of 10 rounded to one digit, with 10 representing an order of magnitude (EPA,1994a). In practice, EPA uses the square root of 10 when there are two or four uncertainty factors of 3, yielding a total uncertainty factor of 10 or 100, and we use a value of 3 when multiplying by an uncertainty factor of 10). By EPA RfC guidelines (U.S. EPA, 1994b), no adjustment for differences in pharmacokinetics is necessary in this instance because the blood/air partition coefficient n16 for nPB in the human (7.1) is less than in the rat (11.7), indicating that the delivered dose of nPB into the bloodstream in rats is slightly higher than in humans. Consistent with Appendix J of EPA's RfC guidelines for an inhaled compound that exerts its effects through the bloodstream, EPA applies an uncertainty factor of 1 for pharmacokinetics.

n14 Pharmacodynamics refers to the biochemical and physiological effects of chemicals in the body and the mechanism of their actions.

n15 Pharmacokinetics refers to the activity or fate of chemicals in the body, including the processes of absorption, distribution, localization in tissues, biotransformation, and excretion.

n16 The blood/air partition coefficient is the ratio of a chemical's concentration between blood and air when at equilibrium.

However, EPA recognizes that the lack of an uncertainty adjustment for pharmacokinetic differences between animals and humans rests on a default approach applied to category 3 gases described in Appendix J of its guidelines for deriving an inhalation RfC. This default approach assumes that nPB's toxicokinetics follow a model in which: (1) The toxicity is directly related to the inhaled parent compound in the arterial blood, and (2) the critical metabolic pathways scale across species, with respect to body weight, in the same way as the ventilation rate. Given the hypothesized metabolic pathways for nPB (ICF, 2002a; CERHR, 2002a), it is

plausible that toxicity in rats may be related to a reactive metabolite in the target tissue rather than the blood level of the parent compound. EPA is not aware of any quantitative data on nPB metabolism in humans, or evidence implicating the biologically active agent or mode of action. Some commenters on the June 2003 NPRM stated that EPA should use an uncertainty factor of 1 or 2 to extrapolate from animals to humans (Weiss Cohen, 2003), while others suggested uncertainty factors of 2 or 3 for pharmacokinetics, or an overall uncertainty factor of 10 for rat to human extrapolation because of a lack of information on the metabolism and mode of action of nPB and because the rat is an insensitive model for effects on male reproduction in humans (Werner, 2003; Rusch and Bernhardt, 2003). Commenters provided no data to indicate that (1) the toxicity is not directly related to the inhaled parent compound in the arterial blood, or (2) the critical metabolic pathways do not scale across species, with respect to body weight, in the same way as the ventilation rate. Recent studies provide additional data regarding metabolism of nPB in rats and mice (RTI, 2005), but data on human metabolism are still lacking.

One analysis of these metabolic data suggested that mice are less sensitive to the effects of nPB than rats and hypothesized that humans would also be less sensitive than rats (Stelljes, 2005). However, this analysis makes numerous assumptions about toxic nPB metabolites and metabolic activation pathways that have not been confirmed by experimental data. A review of this **[*30185]** analysis is available in the public docket (ICF, 2006c). Despite the difference in metabolic pathways for nPB in mice and rats (RTI, 2005), EPA finds no significant species-specific differences in toxicity exist between rats and mice at inhaled concentrations <500 ppm for 13 weeks (NTP, 2003; ICF, 2006b). These metabolic and subchronic inhalation studies conducted under the National Toxicology Program did not specifically examine for reproductive toxicity or nPB metabolism in target organs that control reproductive function. In summary, there are little available data about the metabolic activation or reactive metabolites responsible for reproductive toxicity in rodents. Similarly, for nPB, there is little information available about differences and similarities between rodents and humans. Given this circumstance, EPA assumes, in the absence of evidence to the contrary, that nPB toxicity is directly related to the inhaled parent compound in the arterial blood and that the critical metabolic pathways scale across species in a manner similar to the ventilation rate. Therefore, the Agency is proposing to apply an uncertainty factor of 1 to account for interspecies differences in pharmacokinetics.

EPA requests additional data and comment from the public on the pharmacokinetics, metabolism, and mode of action of nPB that will help determine whether an interspecies uncertainty factor greater than the default value of 1 is warranted to account for pharmacokinetics. If data become available indicating that nPB does not conform to the constraints assumed by the default pharmacokinetic model in the RfC guidelines, we would revise our risk assessment for nPB as necessary, and apply an uncertainty factor for pharmacokinetics consistent with the RfC guidelines in extrapolating from animal to humans. Depending on the resulting difference in the acceptable exposure levels, we would also revise our acceptability determinations accordingly. Given the available data on the blood/air partition coefficient and EPA RfC guidance in the absence of other information, EPA is applying the same rationale used for other compounds reviewed under EPA's SNAP program with a comparable amount of data where an uncertainty factor of 1 for pharmacokinetics was applied. To account for uncertainty in pharmacodynamics of nPB, EPA is applying the default uncertainty factor of 3. This follows the procedures in EPA's RfC guidelines for situations where there are no data to compare pharmacodynamics in rats versus humans (U.S. EPA, 1994b). Recently published data on humans and rodents do not decrease the uncertainty regarding the pharmacodynamics of nPB; therefore, modification of the uncertainty factor of 3 for differences between species is not justified.

One commenter stated that EPA did not cite any data that describes the size, condition, or very existence of a subpopulation of men especially sensitive to the effects of nPB. In addition, this commenter asserted that sensitive populations are not traditionally considered when deriving an occupational exposure limit, and that EPA has never mentioned a concern with sensitive subpopulations in previous SNAP reviews.

EPA disagrees with the comments. There are preexisting reproductive conditions as well as significant variability in fertility among otherwise healthy adults in the workplace. Women over age 35 and men over age 40 have fertility rates up to three times lower than those of people in their twenties, with effects on the ovarian cycle and on sperm motility as major factors changing with increasing age for women and men, respectively (Dunson *et al.*, 2002). Adding damage from other factors, such as smoking or occupation exposure to chemicals such as nPB, therefore, can potentially harm an individual's ability to reproduce further (Dunson, *et al.* 2002). In addition, we note that EPA has used uncertainty factors in the past to protect

sensitive subpopulations on other chemicals reviewed under the SNAP program (e.g., trifluoroiodomethane at 69 FR 58907, October 1, 2004). For deriving AELs from health endpoints such as liver effects and neurotoxicity, the SNAP program typically has assigned an uncertainty factor of 1 for sensitive subpopulations because we assume that individuals who are especially susceptible to these effects will have greater difficulty working than most people. However, there is no connection between the ability to reproduce and the ability to work in the industrial sectors discussed in this rule. Thus, we find it appropriate to apply an uncertainty factor greater than 1 for reproductive effects.

Some commenters on the June 2003 NPRM said that an uncertainty factor of 1 is appropriate for variability within the working population because sensitive subpopulations will not be present in the working population (Stelljes, 2003, Morford, 2003f). Other commenters stated that there will be very little difference in variability between the worker population and the general population and that it is unclear why EPA selected an uncertainty factor of 3 instead of 10 (Werner, 2003). Commenters suggested uncertainty factors for variability in the working population of 1, 2, and 5 (Stelljes, 2003; Weiss Cohen, 2003; Werner, 2003).

EPA's RfC guidelines recommend an uncertainty factor of 10 to account for intraspecies variability within the general population. However, in deriving an acceptable exposure limit, EPA's focus is on worker exposure, which excludes some particularly vulnerable populations, such as children, most adolescents, and the elderly. Thus, we believe that a full uncertainty factor of 10, as for the general population, may be higher than necessary to protect workers. However, because of variability in reproductive function due to factors present among workers, such as aging, smoking, and sexually transmitted disease, and because there is no screening of workers that would make workers more likely to have healthy reproductive systems than non-workers of the same age, we believe than an uncertainty factor of 1 is not sufficiently protective. Under EPA guidelines, 3 is a default value for an uncertainty factor where there is indication that a value less than an order of magnitude (10) but greater than one is appropriate, and where the available data are not sufficiently quantified to select a specific value. Therefore, EPA is again proposing to assign an uncertainty factor of 3 to account for difference between individuals in the working population.

The uncertainty factors of 3 for animal-human extrapolation and 3 for variability within the human working population (each representing the square root of ten, half an order of magnitude) yield a composite uncertainty factor of 10. This factor was applied to all HECs derived from reproductive studies summarized in Table 6 in section IV.E.1 above. The resultant values are higher than the value that would have been obtained had EPA used the TLV of 10 ppm developed by the ACGIH. EPA believes that the benchmark dose approach more accurately characterizes the observed effects and provides a more robust utilization of the data.

D. Other Analyses of nPB Toxicity

Analyses Reviewed During Preparation of June 2003 NPRM

One commenter on the June 2003 NPRM stated that documents by Drs. Doull, Rozman, Stelljes, Murray, Rodricks, and the KS Crump Group were not acknowledged (Morford, 2003f, g, and h). EPA specifically mentioned **[*30186]** and responded to the occupational exposure limit recommendations from Drs. Rozman, Doull, and Stelljes in the preamble to the June 2003 NPRM at 68 FR 33298-33299. In addition, EPA included more detailed written responses to these derivations and the evaluation by Dr. Rodricks in the online docket prior to proposal (EPA-HQ-OAR-2002-0064-0017, -0018, and -0019). We considered these documents in preparation of the June 2003 proposal as well as this proposal.

In general, we disagree that the neurotoxicity endpoint selected by Drs. Rozman and Doull is the most appropriate endpoint for setting an AEL and we agree with Dr. Stelljes that sperm motility in the F1 offspring generation of the WIL, 2001 2-generation study is an appropriate endpoint. We agree with a number of these documents that data from the F1 generation may be conservative because workplace exposure would not include exposure to the F1 animals during the four-week period from weaning to sexual maturity. However, EPA believes that because of the potential for *in utero* effects that would only be seen in the offspring generation, looking only at the F0 parental generation could underestimate the adverse health impacts of a chemical. Therefore, it was appropriate for us to consider effects seen in both the F0 parental generation and the F1 offspring generation. Further, effects on sperm motility in the parental and offspring generations are seen at levels generally consistent with multiple reproductive effects seen in both generations and both

sexes exposed to nPB, such as estrous cycle length, lack of estrous cycling, the number of estrous cycles in a 3-week period, and the number of live pup births (TERA, 2004; ICF, 2006a; SLR International, 2001; Stelljes and Wood, 2004). We believe that the document from the K. S. Crump group, a survey of the ratio of points of departure to TLVs set by the ACGIH, is not relevant now that the ACGIH has issued a TLV specifically for nPB. ACGIH appears to set an AEL for nPB that is a factor of 10 lower than the endpoint cited as lowest (100 ppm for effects on pup weight) (ACGIH, 2005). Thus, ACGIH has used an approach for nPB consistent with the total uncertainty factor of 10 assigned by EPA. In general, we find that these documents submitted by the commenter assigned uncertainty factors in a manner inconsistent with EPA guidance. This would result in a higher AEL than we would determine following the approach EPA has used on other chemicals, as well as an AEL that in our view would not sufficiently protect human health from nPB's effects because of multiple sources of uncertainty in available data (*e.g.*, variability within the working population, differences between animals and humans in how nPB affects the reproductive system).

Since the 2003 NPRM, a number of reviews of nPB toxicity have been issued, several of which include recommendations for occupational exposure limits. CERHR, 2003a and 2004a are similar to CERHR, 2002a, the expert panel report for nPB for the Center for the Evaluation of Risks to Human Reproduction (CERHR). CERHR, 2003b and 2004b are similar to CERHR, 2002b, the CERHR expert panel's report for iPB. These documents discuss the usefulness of data in available studies for assessing nPB's health impacts and establish No Observed Adverse Concentration levels of 100 ppm for both male and female reproductive effects in animals, but do not derive an AEL. Rozman and Doull, 2005 derived an AEL of 25 ppm for nPB based on neurotoxicity, using more recent information than Rozman and Doull, 2002.

The Stelljes and Wood (2004) analysis is similar in its results to SLR International (2001), a study by the same authors. EPA previously reviewed SLR International, 2001 in developing the June 2003 NPRM. Both studies by Stelljes and Wood concluded with a recommended AEL of 156 ppm, based on male reproductive effects and uncertainty factors of 1 in driving the AEL. Stelljes (2005) reviews RTI's 2005 study on metabolism of nPB in mice and rats and other literature and speculates that humans should be less sensitive to nPB than either mice or rats based on differences in metabolite production. Stelljes (2005) recommends that no uncertainty factor is required to extrapolate from animals to humans and that an uncertainty factor of no more than 2 is appropriate to account for differences within the working population. All of these documents assigned uncertainty factors in a manner that is not sufficiently supported by the available data and that is inconsistent with EPA's guidance. For example, Stelljes (2005) discusses metabolic data in rats and mice from RTI, 2005 and concludes that on this basis, the uncertainty factor for extrapolation from animals to humans should be 1. However, the metabolic data relate to pharmacokinetics--the activity of chemicals in the body--and do not address EPA's proposed uncertainty factor of 3 related to pharmacodynamics (the biochemical and physiological effects of chemicals in the body and the mechanism of their actions). Using the AEL from one of these documents would result in a higher, less protective AEL than we would determine following the approach EPA has used for other chemicals under the SNAP program and would not consider multiple sources of uncertainty in health effects (i.e., variability within the working population and differences between animals and humans in how nPB affects the reproductive system). Thus, we are concerned that the AELs based on these documents would not be sufficiently protective and would result in an inappropriate acceptability decision. Detailed reviews of these documents are available in the public docket.

Toxicological Excellence in Risk Assessment (TERA), 2004 reviews other AEL derivations for nPB, performs a benchmark dose (BMD) analysis, and recommends an AEL of 20 ppm based on live litter size. This analysis is consistent with EPA guidance for BMD modeling and for assigning uncertainty factors. A review of this document is available in the public docket (ICF, 2004c).

ICF (2004b, 2006a) derived an AEL for nPB based upon female reproductive effects. ICF (2004b, 2006a) discussed the relevant literature (Ichihara *et al.,* 1999, 2002, 2004a, 2004b; Sekiguchi, 2002; Yamada *et al.*, 2003; WIL, 2001) and calculated mean estrous cycle length and the mean number of estrous cycles occurring during a three-week period at different exposure levels in the WIL, 2001 2-generation study. ICF (2004b, 2006a) found statistically significant reductions in the number of estrous cycles in a three-week period, both including and excluding females that had stopped their estrous cycles, at 250, 500, and 750 ppm in the F0 parental generation and at 500 and 750 ppm in the F1 generation. ICF (2004b, 2006a) conducted BMD modeling and calculated BMDL values of the number of estrous cycles in a three-week period that

varied from 102 to 208 ppm, depending upon the model used and the benchmark criteria selected. All data were calculated based on the mean reductions in estrous cycle number calculated from the WIL, 2001 study. Values were calculated for the F0 generation; the number of data for the F1 generation was too small for statistical analysis. The BMDLs that ICF calculated for the number of estrous cycles in a three-week period were 162 ppm and 208 ppm, depending on the benchmark response criteria (10% change in response vs. one standard **[*30187]** deviation) and using a linear-heterogeneous model.

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) listed both nPB and iPB as reproductive toxins on the basis of developmental, male reproductive, and female reproductive toxicity under the State's Safe Drinking Water and Toxic Enforcement Act of 1986, also known as Proposition 65 (OEHHA, 2006). Under this law, California is required to list chemicals known to be carcinogenic or to be reproductive toxins and to update that list at least annually.

The American Conference of Government Industrial Hygienists (ACGIH) issued a recommended Threshold Limit Value<TM> (TLV) of 10 ppm (time-weighted average) for nPB (ACGIH, 2005). ACGIH summarized numerous studies showing different effects of nPB and identified no observed effect levels (NOELs) of 200 ppm for hepatotoxicity (ClinTrials, 1997b) and less than 100 ppm for developmental toxicity, as evidenced by decreased fetal weight (Huntingdon Life Sciences, 2001).

OSHA has not developed a permissible exposure limit (PEL) for nPB that EPA could use to evaluate toxicity risks n17 from workplace exposure. In prior SNAP reviews, EPA has used ACGIH TLVs where available in assessing a chemical's risks and determining its acceptability if OSHA has not set a PEL. ACGIH is recognized as an independent, scientifically knowledgeable organization with expertise in issues of toxicity and industrial hygiene. However, in this case, EPA believes that ACGIH's TLV for nPB of 10 ppm has significant limitations as a reliable basis for an acceptable exposure limit, especially given the availability of other, more comprehensive analyses described in this proposal. First, according to the authors of the Huntingdon Life Sciences study, the decrease in fetal weight was an artifact of sampling procedure that biased the data (test animals were only sacrificed at the end of the day rather than at random). The CERHR expert panel excluded "aberrantly low" fetal weights from one litter in this study and calculated a BMDL greater than 300 ppm for this endpoint after removing those outlier data (CERHR, 2002a, 2003a, and 2004a). TERA calculated a similar BMDL when analyzing the same data set (TERA, 2004). Further, the reference list in the documentation on the TLV indicates that ACGIH did not review and evaluate all the studies available prior to the development of the recommended exposure limit. For example, key supporting articles that reported disruption of estrous cycles (Yamada *et al.*, 2003 and Sekiguchi *et al.*, 2002) were not discussed in the TLV documentation. Further, ACGIH did not provide sufficient reasoning for the selection of the chosen endpoint over others (e.g., reproductive toxicity and/or neurotoxicity). The lack of discussion of applied uncertainty factors also prevents a determination of how ACGIH arrived at a TLV of 10 ppm. In summary, EPA is not basing its proposed acceptability determination for nPB on the ACGIH TLV because: (1) Other scientists evaluating the database for nPB did not find the reduced pup weight to be the most sensitive endpoint; (2) benchmark dose (BMD) analysis of the reduced pup weight data (CERHR, 2002a; TERA, 2004) results in a higher BMDL (roughly 300 ppm) than those for reproductive effects; and (3) ACGIH may not have reviewed the complete body of literature as several studies discussing neurotoxicity and female reproductive effects were omitted from the list of references. A number of reviews of this document are available in the public docket (ICF, 2004d; O'Malley, 2004).

n17 Vendors of nPB-based products have recommended a wide range of exposure limits, from 5 ppm to 100 ppm (Albemarle, 2003; Chemtura, 2006; Docket A-2001-07, item II-D-19; Enviro Tech International, 2006; Farr, 2003; Great Lakes Chemical Company, 2001).

We note that, even if EPA had selected the ACGIH TLV as our basis for assessing the risks of nPB, we would have proposed the same determinations. In the specific coatings application that we propose to find acceptable subject to use conditions at the Lake City Army Ammunition Plant, exposure data showed an ability to meet an exposure level of 10 ppm, with the vast majority of measurements below that value. Thirty-four of 35 samples had concentrations below 10 ppm, and the mean concentration for the plant was less than 4 ppm (Lake City Army Ammunition Plant, 2004). For the aerosol and adhesive end uses, it would be even more difficult to achieve an exposure level of 10 ppm than to achieve a level in the range that EPA is considering (17 to 30 ppm). Thus, we would have proposed the same decisions for nPB of acceptable, subject to use conditions for coatings and unacceptable for aerosols and adhesives using the ACGIH's TLV

of 10 ppm to assess health risks. Despite some flaws in its derivation, the TLV of 10 ppm is less than two-fold lower than the low end of the range of acceptable exposure levels based on the most sensitive reproductive endpoints. This small difference is well within the uncertainty required to extrapolate a benchmark dose from an experimental study in rats to an occupational exposure limit in humans.

E. Community Exposure Guideline

In this proposal, EPA is using a community exposure guideline (CEG) of 1 ppm to evaluate potential health risks among populations living near facilities using nPB. This community exposure guideline is an estimate of a continuous inhalation exposure (averaged over 24 hours per day, 7 days per week) to the general public (including sensitive subgroups) that is likely to be without an appreciable risk of adverse health effects during a lifetime.

Based on EPA risk assessment guidelines (US EPA, 1994b), the CEG was derived using the lowest BMDL from effects listed in Table 6 as the point of departure (110 ppm for vacuolation in the liver of animals in the F1 generation of WIL, 2001). The HEC was calculated as follows:

110 ppm x (6 hours exposure in study/24 hours avg time) x (7 days/7 days) = 28 ppm

EPA used an uncertainty factor of 3 for extrapolation from animals to humans, as discussed above in section VI.A, and an uncertainty factor of 10 for variability within the general population, consistent with EPA's RfC guidelines. Dividing the HEC of 28 ppm by 30 yields a community exposure guideline of approximately 1 ppm. If we had used sperm motility (HEC of 42 ppm based on a BMDL of 169 ppm) or number of estrous cycles (HEC of 40 ppm based on a BMDL of 162 ppm) as starting points, we would calculate the same approximate CEG value. We note that, following RfC guidelines, EPA's community exposure guideline includes a number of conservative assumptions, including exposure adjustments to protect an individual exposed for up to 24 hours a day for 70 years (U.S. EPA, 1994b, p. 1-5).

EPA evaluated general population exposure using EPA's SCREEN3 (U.S. EPA, 1995b) air dispersion model to assess the likely maximum concentration of nPB from single sources. n18 EPA used data collected from **[*30188]** actual facilities (Swanson, 2002) to characterize two scenarios: (1) A typical large, high-use adhesive application facility where the closest resident is 100 meters away; and (2) a smaller facility with average-use adhesive application in an urban area, where the nearest resident is only 3 meters away. The results indicated that modeled exposures in either scenario did not exceed the CEG of 1 ppm. The highest exposure modeled was 0.24 ppm at a distance of 3 meters away from the source in the urban scenario, while most other exposures were at least an order of magnitude lower (ICF, 2003; ICF, 2006a). Because the community exposure guideline was not exceeded for any of the exposure scenarios in this conservative screening approach, EPA has concluded that nPB exposure to populations living close to facilities using nPB is not a concern for purposes of determining the acceptability of nPB under the SNAP program.

n18 We performed the modeling for a facility using nPB-based adhesives because the nPB emissions from this type of facility were expected to be higher than those from facilities using nPB for other end uses. Thus, if a facility using adhesives would not result in emissions exceeding the CEG, facilities using nPB in aerosols or in metals, electronics, or precision cleaning also would not result in emissions exceeding the CEG.

VI. What listing is EPA proposing for each end use, and why?

In this rule, EPA is proposing to find nPB unacceptable in adhesive and aerosol solvent end uses, and acceptable subject to use conditions in the coatings end use. The proposed listings, summarized in Table 9, are intended to allow the use of nPB where it does not pose a human health risk significantly greater than other substitutes and prohibit nPB's use where nPB exposure cannot be maintained, or is unlikely to be maintained, at even the highest level considered in this proposal (i.e., 30 ppm). We also are taking comment on an alternate approach of finding nPB acceptable subject to use conditions in the above end uses (see Section VII.A).

Table 9.--Proposed Decisions by End Use and Sector

For nPB in this sector and end use:	Our proposal is to list nPB as:	And our proposed alternate approach is:
Aerosols:		
Aerosol solvents	Unacceptable	Acceptable, subject to use conditions. fn2
Adhesives, Coatings, and Inks:		
Coatings	Acceptable, subject to use conditions fn1	Acceptable, subject to use conditions. fn2
Adhesives	Unacceptable	Acceptable, subject to use conditions. fn2

fn1 Use of nPB in this end use is limited to coatings at facilities that, as of May 30, 2007, have provided EPA information demonstrating their ability to maintain acceptable workplace exposures (i.e., the Lake City Army Ammunition Plant).

fn2 Use conditions would include proposed requirements that users must (1) meet an exposure limit of 20 ppm on an eight-hour time-weighted average, (2) monitor workers' exposure to nPB using a personal breathing zone sampler on an eight-hour time-weighted average initially and periodically (every 6 months or longer, depending on the concentration during initial monitoring), and (3) keep records of the worker exposure data on site at the facility for at least three years from the date of the measurement.

A. Aerosol Solvents

In this rule, EPA proposes to find nPB unacceptable in the aerosol solvent end use. There are a number of aerosol solvent alternatives that do not pose any risk for ozone depletion or for ground level smog formation. n19 EPA's greatest concern with nPB-based aerosols is that users of nPB as an aerosol solvent cannot reliably maintain exposures at sufficiently low levels to ensure that workers are protected. This finding is based on measured exposure data and model estimations indicating the likelihood of elevated concentrations associated with nPB-based aerosols given typical ventilation conditions. A number of other acceptable solvent alternatives are available that can be used at exposure levels below their respective acceptable exposure limits.

n19 Smog, also known as ground-level ozone, is produced from emissions of volatile organic compounds that react under certain conditions of temperature and light.

Ventilation conditions are an important consideration in evaluating potential risks within this end-use category. "Benchtop cleaning" of individual parts, which is feasible under exhaust hoods or in spray booths with adequate ventilation, comprises 25% or less of the market involving ODS substitutes for aerosols (U.S. EPA, 2004). According to industry information and several commenters, the majority of the market for nPB-based aerosols involves in-place applications requiring a portable aerosol, such as cleaning energized electrical contacts and switches, maintenance in underground mines, or cleaning active elevator motors (CSMA, 1998; U.S. EPA, 2004; Williams, 2005). These applications often occur in tightly confined spaces where it is not feasible to install ventilation equipment or remove parts to ventilated areas (CSMA, 1998; Linnell, 2003; Werner, 2003). Other acceptable substitutes, such as blends of HFEs or HFCs and trans-dichloroethylene, are available in these end uses. One commenter also suggested that a user of an nPB-based aerosol will assume that they are being provided with a product that offers similar margins of safety as the product being replaced (i.e., HCFC-141b) and therefore can be used under the same conditions (Werner, 2003).

The likelihood that nPB aerosol solvents would be used in poorly ventilated spaces is of particular concern given the likelihood of elevated exposure levels. The exposure data from aerosol solvent use are extremely limited. These data are from simulations of a number of situations where nPB might be used, such as benchtop cleaning of electronics and cleaning automotive brakes, rather than data from facilities currently using nPB in manufacturing or maintenance processes. Thus, the available exposure data may not be

representative of ventilation levels normally used with nPB-based aerosols and may not adequately represent exposure levels during in-place cleaning, industry's most common application for nPB-based aerosols. The distribution of exposure levels in the seven samples ranging from 5.5 to 32 ppm corresponded to the range of ventilation rates reported--0, 300, 640, and 1900 cfm--with the highest ventilation rate resulting in the lowest exposure levels and the lower ventilation levels resulting in the values above 30 ppm. The ventilation rate most consistent with use in a confined space for in-place cleaning, 0 cfm, resulted in half the exposures (one of two) exceeding 30 ppm. The highest ventilation rate, 1900 cfm, occurred at a vented booth, which would not be feasible to install for in-place cleaning applications--the majority of applications for nPB-based aerosols. The middle ventilation rates of 300 and 640 cfm occurred during use of a fan for an entire room (regional ventilation), as might be expected for benchtop cleaning (Confidential submission, 1998), but not for in-place cleaning in confined spaces. In modeling nPB exposure from aerosol solvent use at a low ventilation rate of **[*30189]** 450 cfm, a level that might be expected during benchtop cleaning, 8-hour average concentrations of 16.5 to 33 ppm are predicted, depending on the amount of nPB used (ICF, 2006a). Exposure levels for confined spaces with even lower ventilation rates, as we would expect for in-place cleaning, would be even higher, likely exceeding the high end of the range that EPA is considering. Short-term exposures of 370 and 1,100 ppm taken from workers' collars in a room with regional ventilation at 640 cfm, when averaged over an 8-hour period, resulted in exposure levels of 12 and 34 ppm. These exposures occurred as a result of using nPB over a period up to 15 minutes, so it is likely that users would have greater exposure than 30 ppm if they used nPB for longer than 15 minutes per day, as with multiple uses. The available data sets have a small sample size, may not be representative of in-place cleaning in confined spaces, and do not provide EPA with convincing data that nPB is likely be used safely, at exposure levels at or below the highest level in the range we are considering for evaluation of acceptability.

EPA is concerned that many, and perhaps most, uses of nPB aerosol solvents result in a high probability of exposures at or above even the upper end of the range of exposures that the Agency is considering to be potentially acceptable. EPA is aware of no data on ventilation levels demonstrating that most users of aerosol solvents, or of nPB in particular, would use aerosols in locations with sufficiently high ventilation levels to protect human health (e.g., 1900 cfm or greater). We request data on worker exposure levels, typical ventilation rates, and patterns for usage of nPB-based aerosols, considering both benchtop and in-place use.

EPA has found numerous other aerosol solvents acceptable. These aerosol solvents can be used safely in a manner consistent with their respective acceptable exposure limits. This is highlighted in a study comparing concentrations of eight different chemicals that are acceptable under the SNAP program in aerosol formulations: HFE-7100, HFE-7200, trans-1,2-dichloroethylene, HCFC-225ca and -225cb, acetone, pentane, and HFC-134a. In this study, with ventilation of only 48 cfm, 8-hr TWA exposure from the different chemicals varied from 35.5 ppm to 194.0 ppm, and all chemicals met their respective recommended exposure levels (ICF, 2006a). As discussed above in section V.A, when these concentrations are adjusted for the chemicals' respective molecular weights, they would correspond to nPB concentrations of 29.5 to 394.4 ppm, which is at or above even the highest level the Agency would consider acceptable. The ventilation level in this study is closer to what we would expect in a confined space where fans or vents cannot be installed, as for in-place cleaning. Based on these considerations, the Agency believes that nPB used as an aerosol solvent would impose significantly more risk to human health than other alternatives available for this end use.

B. Adhesives

EPA proposes to find nPB unacceptable in the adhesive end use. As for aerosol solvents, we found that some alternative adhesive formulations could reduce particular environmental risks more than nPB, such as generation of ground level "smog" or ozone depletion potential. However, we find the greatest concern in this end use is with nPB's human health effects. We propose to find nPB unacceptable in adhesives because it poses significantly greater risk to human health as compared to other available alternatives in this end use.

In the June 2003 NPRM, we initially proposed to find nPB acceptable in adhesives based on the SNAP program principle that "EPA does not intend to restrict a substitute if it poses only marginally greater risk than another substitute * * *. The Agency also does not want to intercede in the market's choice of available substitutes, unless a substitute has been proposed or is being used that is clearly more harmful to human health and the environment than other alternatives." (68 FR 33294, citing the original March 18, 1994 SNAP

rule at 59 FR 13046). At the time of the proposal, we considered data from NIOSH monitoring and health hazard evaluations for three facilities using nPB-based adhesives. At two of the three facilities, NIOSH worked together with the companies to install state-of-the-art ventilation equipment. Looking at exposure data from all workers after ventilation improvements, we believed it would be possible for facilities to meet the proposed AEL of 25 ppm (68 FR 33294).

. One public commenter suggested that EPA should reconsider whether industrial exposures consistently occur and/or can be controlled to a level at or below 25 ppm (Werner, 2003). We reevaluated the exposure data for the two plants that had improved their ventilation, focusing on exposure to the workers that receive the highest exposures because they directly spray the nPB-based adhesive. We found that, even in the best case, a substantial number of workers spraying nPB-based adhesives would be exposed above the highest level in the range we are considering.

. NIOSH investigators initially reported that mean exposures to nPB ranged from 60 to 381 ppm (8-hour time weighted averages) at three different foam-fabrication facilities using nPB-based adhesives (NIOSH, 2000a, 2000b, 2001, 2002a, 2002b, 2003a). In one facility, average (mean) nPB exposures were reduced from 169 ppm to 19 ppm, following installation of ventilation equipment (NIOSH, 2000b). Although use of spray booths at this facility reduced the average exposure level to 19.4 ppm for all workers, the majority of the sprayers directly using nPB-based adhesives still would be exposed at unacceptably high levels. Out of fourteen sprayers at the Custom Products facility:

. Six, or 43% of sprayers, would be exposed to more than 30 ppm.

. Nine, or 64% of sprayers, would be exposed to more than 25 ppm.

. Ten, or 71% of sprayers, would be exposed to more than 20 ppm.

. Eleven, or 79% of sprayers, would be exposed to more than 15 ppm.

. Thirteen, or 93% of sprayers, would be exposed to more than 10 ppm.

At another facility using nPB-based adhesives, the average exposure was reduced from 58 pm to 19 ppm after the company installed ventilation recommended by NIOSH (NIOSH, 2001). Data on exposure for sprayers found fewer individuals receiving high exposures than at the facility monitored in NIOSH (2000b), but 65% (22 of 34) of exposure samples for sprayers were higher than 15 ppm, 33% (11 of 34) were higher than 20 ppm and 15% (5 of 34) were higher than 25 ppm after improving ventilation.

Overall, 42% of sprayers in these two facilities using nPB-based adhesives were exposed to concentrations of nPB greater than 20 ppm (21 of 48 workers) and 23% (14 of 48 workers) were exposed to more than 25 ppm, even after installing state-of-the-art ventilation with assistance from NIOSH. Sprayers had significantly higher individual exposures than workers who did not work directly with the nPB-based adhesive.

In response to public comment and additional information available to EPA since the June 2003 NPRM, we now propose that use of nPB-based adhesives poses significantly higher risks to human health than other available adhesives. Since the June 2003 NPRM, there have been a number of reports of **[*30190]** workers working with nPB-based adhesives that have suffered adverse, persistent neurological effects that resulted in hospitalization (Beck and Caravati, 2003, and Majersik *et al.*, 2004, 2005; Calhoun County, 2005; Miller, 2005; Raymond and Ford, 2005). Based on data from actual facilities using adhesives, it is estimated that a facility using nPB with average adhesive application rates and average ventilation rates would have exposure levels of approximately 60 ppm on an 8-hr time-weighted average (ICF, 2006a). Modeling of exposures at high adhesive application rates and average or lower ventilation rates resulted in exposures of approximately 250 to 2530 ppm (ICF, 2006a). We believe these modeling results show that most adhesive users would exceed acceptable exposure levels by significant margins and that it is unlikely that adhesive users would be able to use nPB safely.

Considering the exposure data for nPB-based adhesives, we believe it is unlikely that, even with improved ventilation, adhesive users could reduce exposures to acceptable levels on a consistent basis. In the best case seen, a facility with low to average initial exposure levels was able to reduce exposures to the middle of the range EPA is considering after extensive assistance from NIOSH in installing state-of-the-art

ventilation. We expect that many facilities will begin with higher exposure levels and will not have the same level of assistance to improve ventilation, thus making it unlikely that they would achieve acceptable exposures. Given the information above, we are concerned that nPB-based adhesives cannot be reliably used in a manner that protects human health. We request comment and further data on whether it is feasible to use nPB-based adhesives with worker exposure levels consistently at or below any of the values in the range of exposure levels that EPA is considering potentially acceptable (i.e., 17 to 30 ppm).

The available information indicates that all acceptable carrier solvents in adhesives other than nPB have projected or actual exposure less than the appropriate workplace exposure limit EPA used in finding those substitutes acceptable. Examples of other carrier solvents currently used in adhesives and acceptable under the SNAP Program include hydrocarbon solvents, acetone, methylene chloride, and water. EPA finds that there are other available alternatives that pose significantly less risk to human health and the environment compared to nPB in the adhesives end use.

During the public comment period on the June 2003 NPRM, one commenter representing the adhesives industry stated that there are some small but critical applications that require nonflammability and high solvency (Collatz, 2003). The commenter did not specify what those applications are, and whether there was information showing that other types of adhesives, such as those using water, flammable solvents, or methylene chloride, are technically infeasible in these applications. We request comment and data on whether there are any unique applications in the adhesives end use for which there are no technically feasible alternatives other than nPB and thus, for which nPB should be allowed. If so, and if determined that nPB should be unacceptable except where no other substitutes are feasible, we would consider finding nPB acceptable subject to narrowed use limits, with requirements for each end user to perform a demonstration that there are no other technically feasible alternatives for their particular site, to install local exhaust ventilation equipment designed to reduce exposures to acceptable levels and to perform worker exposure monitoring. Alternatively, if there was sufficient information provided during the public comment period showing that there are applications in which nPB can be safely used, we would consider finding nPB acceptable in adhesives, subject to use conditions requiring installation of local exhaust ventilation and worker exposure monitoring. This would allow for use of nPB in any applications where it may be used safely if any such applications exist.

C. Coatings

We are proposing to find nPB acceptable, subject to use conditions, for facilities that, as of May 30, 2007, have provided EPA information demonstrating their ability to maintain workplace exposure levels below even the minimum level of the range of exposures that EPA is considering to be potentially acceptable (i.e., 17 to 30 ppm). The SNAP submission with information on coatings was made for a single facility and EPA is unaware of anyone else interested in using nPB in this end use. Therefore, there are currently no analyses indicating whether nPB would pose significantly greater risks in any coating applications other than this facility. Workplace exposure levels to nPB from ammunition sealant at Lake City Army Ammunition Plant ranged from less than 1 ppm up to 21 ppm on an eight-hour time-weighted average. Thirty-four of 35 samples had concentrations below 10 ppm, and the mean concentration for the plant was less than 4 ppm (Lake City Army Ammunition Plant, 2004). The vast majority of measurements show worker exposure well below the lowest level in the range of exposures that EPA is considering. Thus, we believe that nPB can be used as safely as other acceptable solvents used at their acceptable exposure limits under the conditions at this facility.

Other acceptable substitutes for ozone-depleting substances in coatings, in general, include oxygenated solvents, hydrocarbon solvents, terpenes, hydrofluoroethers 7100 and 7200, benzotrifluorides (include parachlorobenzotrifluoride), monochlorotoluenes, trans-1,2-dichloroethylene, chlorinated solvents, water-based formulations, and high-solids formulations. In the particular application for ammunition coatings, the submitter evaluated a large number of alternatives and found that n-propyl bromide was the only one of 29 solvents tested that could meet performance specifications at this facility (Harper, 2005). Thus, it is not clear that there are other substitutes available for this specific application, and exposure data show that in this specific application, nPB can be used in a way that does not pose significantly greater risks to human health compared to other acceptable substitutes in the coatings end use.

VII. What other regulatory options did EPA consider?

EPA considered several different options, but we prefer the approach proposed in this rule. We also take comment on the options discussed below.

A. Alternate Option for Comment: Acceptable With Use Conditions Requiring Exposure Limit and Monitoring

We also take comment on a proposed alternate approach in which nPB would be acceptable subject to use conditions in all the end uses addressed in this action. Under this alternate approach, users would meet an exposure limit, monitor exposure of workers using nPB, and keep records to demonstrate compliance with these requirements. For purposes of this alternative proposal, we selected 20 ppm to use as an exposure limit above which use would be unacceptable, and 10 ppm as an action level that allows reduced exposure monitoring, for the reasons discussed below in section VII.A.1, "Use Conditions and Their Rationale." However, we are soliciting comment on whether a different exposure level within the 17 to 30 ppm range should **[*30191]** be selected. The following requirements would apply at each facility where nPB is used:

Exposure Limit

The owner or operator would be required to ensure that workers using nPB are exposed to no more than 20 ppm on an 8-hour time-weighted average. The exposure limit could be met through engineering controls (e.g., ventilation equipment), work practices, or reduced use of nPB.

Initial Worker Exposure Monitoring

For each facility where nPB is used, the owner or operator of the facility would be required to ensure that personal breathing zone air samples of each nPB user's exposure would be collected on an eight-hour, time-weighted average initially within 90 days after a final rule becomes effective. Monitoring measurements may be taken with an organic chemical monitoring badge on the collar or a tube filled with charcoal on the collar.

Periodic Exposure Monitoring

(1) The owner or operator of the facility would be required to ensure that personal breathing zone air samples of user exposure are collected periodically on an eight-hour, time-weighted average depending on the results of the most recent set of exposure data. A monitoring program could be instituted by the company or by the nPB supplier for that facility. Periodic sampling requirements would be based on the most recent monitoring results, as follows:

Table 10.--Alternative Approach Exposure Levels and Periodic Exposure Monitoring

If exposure measurements for nPB are at this level:	Then the owner or operator:
all measurements at or below 10 ppm	is not required to perform periodic exposure monitoring.
all measurements at or below 20 ppm, with some measurements above 10 ppm	must take personal breathing zone samples again at least once in the next six months.
at least one measurement above 20 ppm	must stop using nPB in the application exceeding the exposure limit until exposure data show that 20 ppm can be consistently met in the vast majority of cases.
unknown, in cases of new workplace conditions increasing exposure or new applications of nPB	must take personal breathing zone samples as a test before using nPB in new industrial applications or conditions, or

Table 10.--Alternative Approach Exposure Levels and Periodic Exposure Monitoring

If exposure measurements for nPB are at this level:	Then the owner or operator:
	within 7 days of an emergency caused by a leak, rupture or breakdown, and use this value to determine the next time monitoring is required.

(2) For periodic monitoring, the owner or operator would be allowed either to monitor each nPB user's exposure, or to monitor exposure of a representative nPB user in each job classification in a work area during every work shift, where the monitored nPB user is expected to have the highest exposure.

(3) The owner or operator would be allowed to discontinue the periodic 8-hour TWA monitoring for nPB users at the facility where at least two consecutive sets of measurements taken at least seven days apart are below 10 ppm.

Monitoring for New Conditions or Applications

Whenever there is a change in workplace conditions that may increase exposure or whenever a new application of nPB is introduced, the owner or operator would be required to take personal breathing zone samples accounting for all nPB users as a test before using nPB in manufacturing or repair. These could be either samples for each nPB user or samples representing each job classification in a work area during a work shift, so long as the samples are based on the user with the likely highest exposure. Examples of changes in workplace conditions that may increase exposure include changes in production, process control equipment, or work practices, or a leak, rupture, or other breakdown. n20 Examples of introduction of a new application of nPB include aerosol contact cleaning in a location with regional ventilation or natural ventilation, where previous measurements were carried out on workers in a location with local ventilation. If the change occurs because of an unpredictable emergency, then the owner or operator would need to ensure exposure monitoring takes place within 7 days of the change.

n20 See 29 CFR 1910.1052(d)(4)(i).

Sampling Methods and Accuracy

Exposure samples would be required to be analyzed either by NIOSH method 1003 for halogenated hydrocarbons or method 1025 for 1-bromopropane and 2-bromopropane or by another method that is accurate to +/-25% at the 95 percent confidence level.

Recordkeeping Requirements

The owner or operator of the facility would be required to keep records of the monitored exposure data at the facility for at least three years from the date the measurements were taken for purposes of this rule. These records would be required to be made available in the event of a facility inspection or a request for the data by EPA. Note that the EPA's recordkeeping requirement does not affect OSHA's standard on access to employee exposure and medical records, which requires retaining any exposure records for at least 30 years (29 CFR 1910.1020(d)(ii)).

The regulatory listings by end-use under this alternate approach that the Agency requests comment on would be as follows:

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See illustrations on pages 30192-30193 in original document **[*30194]**

1. Use Conditions and Their Rationale

The major provisions of the use conditions and the related issues that EPA considered in developing the alternate approach that we are taking comment on are as follows:

Exposure limit. A requirement to meet a workplace exposure limit would be an interim measure to ensure that nPB will be used safely until OSHA issues a final permissible exposure limit (PEL) under the Occupational Safety and Health Act. In the event that OSHA issues a final PEL, it would supersede EPA's exposure limit. EPA is specifically deferring to OSHA, and has no intention to assume responsibility to displace OSHA's authority under Public Law 91-596. EPA's exposure limit would not pre-empt the authority of OSHA to take regulatory or enforcement action with respect to exposure to this substance. This is made clear by the Clean Air Act under which EPA would promulgate this regulation (Subchapter VI--Stratospheric Ozone Protection), which provides at 42 U.S.C. 7610 in pertinent part: "* * * this chapter [Chapter 85--Air Pollution Prevention] shall not be construed as superseding or limiting the authorities, under any other provision of law, of the Administrator or any other Federal officer, department, or agency." By issuing an exposure limit for nPB, EPA's intention would be to fill existing regulatory gaps during the interim period of substitution away from ozone-depleting compounds and provide the needed margin of protection for human health and the environment until OSHA develops other regulatory controls or standards under appropriate authorities.

As discussed above in section IV.E.1, EPA is considering exposures within the range of 17 to 30 ppm as potentially acceptable in order to determine whether nPB may be used safely in each end use. For purposes of having a clear compliance target under this alternative approach for public comment, we are using 20 ppm as the exposure limit above which use would be unacceptable. We chose this value because we expect it to be protective against the reproductive and developmental effects identified previously (live litter size, sperm motility, estrous cycles). *Worker exposure monitoring.* The worker exposure monitoring requirements under the use conditions in the alternate approach were modeled after OSHA's requirements for monitoring for methylene chloride. 29 CFR 1910.1052(d). We expect that the regulated community would be familiar with this approach and there might be fewer changes for regulated businesses if OSHA later were to establish a workplace standard for nPB. Because the exposure limit would be an 8-hr TWA value that is derived from studies that measured exposure via inhalation, the proposed use conditions require the owner or operator to monitor 8-hr TWA values that measure workers' exposure in the breathing zone (e.g., samples from a worker's collar). We are not proposing to monitor short-term exposures because acute, short-term exposures of nPB are not of significant health concern, so long as long-term exposures are below the 8-hour TWA limit or potentially acceptable exposure levels (ERG, 2004).

Option for monitoring representative set of workers. Personal breath zone samples could be taken either from each worker using nPB or from a representative n21 set of exposed workers expected to have the highest exposure. Allowing exposure monitoring from representative workers using nPB, rather than requiring separate monitoring for each individual using nPB, would reduce overall compliance burden, while still detecting any exposure levels in excess of the exposure limit and avoiding underestimates of exposure.

n21 In its methylene chloride standard, OSHA defined representative sampling as follows: "The employer has taken one or more personal breathing zone air samples for at least one employee in each job classification in a work area during every work shift, and the employee sampled is expected to have the highest * * * exposure." (29 CFR 1910.1052(d)(1)(ii)(A)).

Initial monitoring. Users already using nPB would need to undergo exposure monitoring no later than 90 days after the date the final rule becomes effective. A user that has never used nPB before would need to perform initial monitoring before beginning to use nPB in the facility's industrial applications.

Periodic monitoring. Monitoring would have to be performed periodically on a schedule based on the results of the most recent set of exposure monitoring data. Monitoring from workers' personal breathing zone would be required during the next six months if an initial measurement finds exposure levels between the action level n22 and the 8-hour TWA exposure limit. No periodic monitoring would be required if initial measurements are below the action level. The action level would be the value that is half the exposure limit, in this case 10 ppm. OSHA standards also set an action level of half the PEL.

n22 The action level is the exposure level that is half the 8-hour TWA exposure limit. In this case, the action level would be10 ppm.

Under the alternate approach, monitoring would no longer be required where the most recent exposure monitoring data found all worker exposures at or below 10 ppm. OSHA rules also reduce monitoring requirements for exposures below the action level because if measured values are that low, it is unlikely that any measurement will exceed the PEL unless a major change to the process occurs.

Monitoring for changes in workplace conditions or nPB use. New monitoring would be required if an event occurs that would make the most recent set of monitoring data no longer representative. EPA would expect that the owner or operator would plan new applications of nPB or changes to control equipment or work practices and would perform a test for worker exposure levels before using nPB on a regular basis in that application. In the case of an emergency, such as a breakdown of ventilation equipment or a leak, we would expect exposure monitoring to be performed as soon as possible, and no later than 7 days after the change in workplace conditions. This period is intended to give an owner or operator time to locate and purchase exposure monitoring equipment in an emergency where the equipment may not already be available at the facility.

Monitoring method and accuracy. We take comment on the use of NIOSH methods 1003 and 1025 (NIOSH, 2003b and c) for analyzing nPB exposure under the proposed alternate approach. Several of the studies that supplied EPA with exposure data used this method and they are standardized methods prepared by NIOSH, a recognized authority on industrial hygiene. In addition, we would allow other methods that are accurate to +/- 25% at the 95 percent confidence level. Based on the accuracy of available methods, most OSHA standards require exposure monitoring accurate to 25% at the 95 percent confidence level, as in the methylene chloride standard (29 CFR 1910.1052(d)(1)(iii)(A)) and other OSHA standards.

Recordkeeping requirements. We would require that users keep records of the worker exposure data for three years from the date the measurement is taken. n23 This would provide information allowing EPA to determine if facilities are complying with the exposure limit and if workers exposed to nPB are sufficiently protected.

n23 OSHA's standard on access to employee exposure and medical records requires retaining exposure records for at least 30 years (29 CFR 1910.1020(d)(ii)), and these requirements would not be affected by this regulation.

Responsibility for meeting requirements. Under the alternate approach, the owner or operator of a **[*30195]** facility using nPB would be responsible for meeting the rule's use conditions.

2. Advantages and Disadvantages of the Alternate Approach

Setting use conditions that require users to meet an exposure limit and to monitor and keep records to demonstrate achieving the limit would protect the health of nPB users while giving industry more flexibility and more options for ODS substitutes, compared to finding nPB unacceptable. This could be especially useful for users of HCFC-141b as an aerosol solvent that are seeking an effective ODS substitute. If there were any situations in which other available alternatives did not provide as good performance, nPB would still be available as an option, provided the use conditions could be met. The monitoring requirements would encourage good industrial hygiene and safe use of nPB.

Considering the list of use conditions above, we believe that setting use conditions requiring an exposure limit, worker exposure monitoring, and recordkeeping would be complex and potentially confusing. Requiring users to meet the exposure limit, although providing greater potential flexibility, also would provide less certainty about how to comply. A user could spend considerable time and expense trying to meet the exposure limit, only to find that it is not achievable.

Given the limited circumstances under which we expect aerosol and adhesive users could meet an acceptable exposure limit and given the availability of other, less toxic alternatives in both of these end uses, EPA's preferred option is to find nPB unacceptable in aerosols and adhesives. Further, considering that without regulatory requirements, the users of nPB at the Lake City Army Ammunition Plant have been operating with the vast majority of exposure levels below 17 ppm, the low end of the range of exposures that

EPA is considering to be potentially acceptable (Lake City Army Ammunition Plant, 2004), it appears unnecessary to require an exposure limit in that application.

B. Regulatory Options Where nPB Would Be Acceptable With Use Conditions Requiring Specific Equipment

We considered use conditions for the adhesive and aerosol solvent end uses that would reduce the human health risks of using nPB by reducing exposure levels with requirements for installation and use of ventilation equipment. We also offer for comment use conditions that would require aerosol dispensing equipment that would reduce exposure levels and that would allow use of aerosol blends with reduced amounts of nPB to maintain acceptable exposure levels.

1. Aerosols

For the aerosol solvent end use, EPA considered proposing a requirement for installation of ventilation equipment. Such a use condition would need to specify and define which kinds of ventilation equipment would be necessary. For example, because one study on exposure levels found that exposure levels reliably fell in or below the range that EPA is considering (i.e., 17 to 30 ppm) only where both local exhaust ventilation and regional ventilation equipment were used, a possible requirement would be for installation of both local exhaust ventilation and regional ventilation. We would define local exhaust ventilation as ventilation that removes vapors from a specific work location using ducts and fans. We would define regional ventilation as ventilation that moves air around in a large working area, such as one or more fans used for an entire room. A problem with requiring the type of ventilation equipment that all facilities must use is that it still might not provide enough ventilation in some situations and in other situations may be unnecessary to meet an exposure limit.

Another approach for aerosols we considered was to require a specific level of ventilation. Possible criteria for the level of ventilation would be the air flow rate, in cubic feet per minute (cfm) or cubic meters per second, or the face velocity at the location where a user would work, in feet per minute (fpm) or meters per second face velocity. Based on both modeling and exposure data from one study (ICF, 2006a; Linnel, 2003), an appropriate air flow rate for nPB-based aerosols would be greater than 1900 cfm and an appropriate face velocity would be 170 fpm. Alternatively, we considered requiring that facilities meet the guidelines for face velocity in spray booths from the ACGIH Ventilation Manual, in the range of 100 to 150 fpm, depending on the specific type of booth (ACGIH, 2002).

These options would appear to provide greater flexibility for industry compared to finding nPB unacceptable in aerosol solvents. However, our understanding is that in most aerosol applications, it might not be feasible to install adequate ventilation, and thus, to reduce human health risks. In the case of benchtop cleaning or degreasing, such as during rework of individual parts that are not yet sufficiently clean, it is possible to transport the part to a hood or spray booth to provide sufficient ventilation. However, for applications that require in-place cleaning such as cleaning energized electrical contacts and switches, maintenance in underground mines, or cleaning hot elevator motors, it is not feasible to install ventilation equipment in place or to remove the parts for cleaning in ventilation equipment (CSMA, 1998; Linnell, 2003). Information available to EPA shows that benchtop cleaning is perhaps 25% or less of the market for the ODS being replaced in aerosols (US EPA, 2004) and that electrical contact cleaning makes up the vast majority of the market for nPB-based aerosols (Williams, 2005); thus, we expect that necessary ventilation cannot be installed in most aerosol applications for nPB. It would be difficult to explain and potentially confusing for users that an aerosol product may be used for cleaning in one location in a facility, but not in another, particularly when the ODS being substituted for could be used in all locations at safe exposure levels. Further, it would be difficult for EPA to enforce use conditions on ventilation equipment, because aerosols are portable and can easily be used outside of the ventilation equipment. Other acceptable substitutes, such as blends of HFEs or HFCs and trans-dichloroethylene, are available in these end uses.

Another option that the Agency considered is finding nPB acceptable as an aerosol solvent, subject to the use condition that the aerosol product must be dispensed from a device or a system that is capable of maintaining acceptable exposure levels. The Agency is aware of at least two remote dispensing systems that could potentially mitigate exposures when used with low-pressure aerosols (Micro Care's Trigger Grip<TM> and Miller Stephenson's Cobra(R) Solvent Spray Cleaning Brush). Vendor data indicates that each aerosol can may last twice as long when using a remote dispensing system, compared to standard aerosol usage,

indicating the ability to halve average exposure levels and reduce total solvent use (Micro Care, 2006). However, these types of systems would only be practical for benchtop cleaning, and not electrical contact cleaning, which comprises the majority of nPB aerosol use. The Agency requests comment on the viability and enforceability of a use condition requiring aerosol dispensing systems or other mitigation devices that could provide sufficient performance while **[*30196]** ensuring acceptable workplace exposure levels of nPB.

Finally, the Agency considered another option by which the use of nPB would be acceptable in aerosol solvent uses, subject to the condition that users may only use blends of no more than fifty percent nPB and the remainder being propellants and other solvents, with manufacturer's recommended exposure guidelines for compounds other than nPB being no lower than 100 ppm. Based on exposure modeling performed on simulations of several commercial blends of nPB and another compound with a higher exposure limit (HFC-365mfc), it appears that users should be able to maintain exposures reliably below the range that EPA is considering for acceptability (i.e., 17 to 30 ppm) when using a blend containing no more than fifty percent nPB by weight at the ventilation levels modeled (ICF, 2006a). We note that the modeling does not consider the possibility that a user might need to use more of a blend with less nPB, since nPB is more aggressive than many other solvents used in aerosols. It also does not address exposure levels in confined spaces as might occur during in-place cleaning with aerosols. We request comment and relevant, empirical data on the 8-hour TWA exposures that can be reliably attained when using blends containing 50% or less of nPB by weight. In order to make this option enforceable, EPA would require users to keep records of nPB-containing aerosol blends they purchase, including the MSDS or other documentation of the proportion of nPB in the blend they use. We request comment on whether this is a feasible, enforceable option and whether it would provide useful flexibility to industry while ensuring adequate health protection.

2. Adhesives

EPA also considered use conditions for ventilation equipment or for specific ventilation levels for use of nPB-based adhesives. However, to date, we have found no study that demonstrates a ventilation option that could consistently achieve even the highest level within the range that EPA is considering for acceptability when using spray adhesives. Even with state-of-the-art ventilation equipment installed with the expert assistance of NIOSH, adhesives users were not able to lower exposure limits sufficient to protect the vast majority of their workers. Modeling of different levels of adhesive usage and ventilation, based on conditions at different facilities indicates that air flow rates would need to be more than 100,000 cfm. Even this high air flow rate might not be sufficient, since an air flow rate of 28,500 cfm resulted in exposure levels of 3.5 to 35 times an acceptable exposure level, depending on the amount of adhesive used (ICF, 2006a, Att. D). Less toxic substitutes such as water-based adhesives and acetone-based adhesives are available in this end use.

VIII. What are the anticipated costs of this regulation to the regulated community?

As part of our rulemaking process, EPA estimated potential economic impacts of this proposed regulation. In our analysis, we assumed that capital costs are annualized over 15 years or less using a discount rate for determining net present value of 7.0%. Because the use condition for coatings still permits nPB's use in the only known coatings application using nPB, we find no additional cost to the user community from this regulatory provision. We found that if this proposed rule were to become final, the cost to the user community of the unacceptability determinations, which are regulatory prohibitions on the use of nPB in adhesives and aerosols, would be in the range of $ 2.3 to $ 6.7 million per year for adhesive users and $ 36.3 to 39.7 million per year for aerosol users.

EPA also estimated the cost to the user community of the use conditions in the proposed alternate approach for aerosols, adhesives, and coatings. The requirements for users to meet an acceptable exposure limit and to perform exposure monitoring would be in the range of $ 42.3 to 67.5 million per year. The upper end of the range of estimated impacts assumes laboratory grade ventilation for aerosols, which we expect to be significantly more expensive than standard industrial fume hoods or spray booths (approximately $ 10,000 compared to $ 1,000 for each hood). For coatings, use of nPB is limited to a single facility that already performs workplace exposure monitoring, and thus, no new costs would be incurred. For aerosols and adhesives, we assumed the installation of fume hoods or spray booths, the use of personal protective equipment, and monitoring for 1.9 to 2.0 times per year on average. Using these assumptions, we calculated the cost of the use conditions in the proposed alternate approach at $ 18.0 to 24.0 million for adhesive users,

and $ 24.3 to 43.5 million for aerosol users. The estimated cost of the use conditions does not consider that some users could choose to switch to other alternatives at a lower cost.

Estimated costs of the proposed regulation and proposed alternate approach are summarized in Table 13. For more detailed information, see section XIII.C. below and EPA's analysis in the docket (US EPA, 2006).

Table 13.--Estimated Costs of Regulatory Options EPA is Providing for Comment

Sector or end use	Requirements under proposed rule	Annual cost of proposed rule	Requirements under alternate approach	Annual cost of alternate approach
Aerosol Solvents	Cease use of nPB and switch to a different ODS substitute	$ 36.3 to 39.7 million	Achieve 20 ppm; exposure monitoring one or two times per year; Recordkeeping	$ 24.3 to 43.5 million.
Coatings	Decision applies to use nPB in coatings at facilities that, as of May 30, 2007, have provided EPA information demonstrating their ability to maintain acceptable workplace exposures	None	Achieve 20 ppm; exposure monitoring, one or two times per year; recordkeeping	None.
Adhesives	Cease use of nPB and switch to a different ODS substitute	$ 2.3 to 6.7 million	Achieve 20 ppm; exposure monitoring, one or two times per year; recordkeeping	$ 18.0 to 24.0 million.
Total		$ 38.6 to 46.4 million		$ 42.3 to 67.5 million.

[*30197]

IX. How do the decisions for EPA's June 2003 proposal compare to those for this proposal?

Table 14 compares the acceptability determination and evidence cited in the June 2003 proposal and this proposal.

Table 14.--n -Propyl Bromide Acceptability Decision

Proposed decision	2003 proposed rule	Current proposed rule--preferred proposal
Industrial End Use #1: Aerosol Solvents	Acceptable, Subject to a Use Condition (Limiting use to nPB formulations containing no more than 0.05% by weight isopropyl bromide; AEL of 25 ppm fn1 on 8-hr TWA recommended	Unacceptable.
Industrial End Use #2: Adhesives	Acceptable, Subject to a Use Condition (Limiting use to nPB formulations containing no more than 0.05% by weight isopropyl bromide; AEL of 25 ppm fn1 on 8-hr TWA recommended	Unacceptable.
Industrial End Use #3: Coatings	Not addressed	Acceptable, Subject to Use Conditions (Decision limited to coatings at facilities that, as of May 30, 2007, have provided EPA information demonstrating their ability to maintain acceptable workplace exposures. fn2

fn1 Proposed acceptable exposure limit of 25 ppm adjust upward from value of 18 ppm based upon nPB's effect on sperm motility from evaluation of the WIL 2001 Study "An Inhalation Two-Generation Reproductive Toxicity Study of 1-Bromopropane in Rats."

(a) ICF, 2001. "Brief Discussion of the BMD Approach: Overview of its Purpose, Methods, Advantages, and Disadvantages." Prepared for U.S. EPA.

(b) ICF, 2002a. "Risk Screen for Use of N Propyl Bromide." Prepared for U.S. EPA, May, 2002.

(c) ICF, 2002b. Comments on the NTP-Center for the Evaluation of Risks to Human Reproduction, Final Report on 1-Bromopropane. Cover Letter Dated 5/9/02.

Also, evaluation of documents by CERHR (2002a, b), Doull and Rozman (2001), Rodricks (2002), Rozman and Doull (2002), SLR International (2001), and others.

fn2 For purposes of this proposal, EPA is considering levels within the range of 17-30 ppm based on the following information on nPB's health effects for purposes of determining acceptability: estrous cycle length at 17 to 22 ppm, live litter size at 20 ppm, and sperm motility at 18 to 30 ppm from evaluation of the WIL

2001 Study "An Inhalation Two-Generation Reproductive Toxicity Study of 1-Bromopropane in Rats" and confirmed by comparison with other studies. Also, considers evaluation of documents by Stelljes and Wood (2004); TERA (2004); ICF, 2006a; ACGIH (2005); Rozman and Doull (2005); Stelljes (2005); and others.

X. How can I use nPB as safely as possible?

Below are actions that will help nPB users minimize exposure levels:

All end uses

. All users of nPB should wear appropriate personal protective equipment, including chemical goggles, flexible laminate protective gloves (e.g., Viton, Silvershield) and chemical-resistant clothing. Special care should be taken to avoid contact with the skin since nPB, like many halogenated solvents, can be absorbed through the skin. Refer to OSHA's standard for the selection and use of Personal Protective Equipment, 29 CFR 1910.132.

. Limit worker exposure to solvents to minimize any potential adverse health effects. Workers should avoid staying for long periods of time in areas near where they have been using the solvent. Where possible, shorten the period during each day when a worker is exposed. Where respiratory protection is necessary to limit worker exposures, respirators must be selected and used in accordance with OSHA's Respiratory Protection standard, 29 CFR 1910.134.

. Use less solvent, or use a different solvent, either alone or in a mixture with nPB.

. Follow all recommended safety precautions specified in the manufacturer's MSDS.

. Workers should receive safety training and education that includes potential health effects of exposure to nPB, covering information included on the appropriate MSDSs, as required by OSHA's Hazard Communication Standard (29 CFR 1910.1200).

. Request a confidential consultation from your State government on all aspects of occupational safety and health. You can contact the appropriate state agency that participates in OSHA's consultation program. These contacts are on OSHA's web site at *http://www.osha.gov/oshdir/consult.html.* For further information on OSHA's confidential consultancy program, visit OSHA's web page at *http://www.osha.gov/html/consultation.html.*

. Use the employee exposure monitoring programs and product stewardship programs where offered by manufacturers and formulators of nPB-based products.

. If the manufacturer or formulator of your nPB-based product does not have an exposure monitoring program, we recommend that you start your own exposure monitoring program, and/or request a confidential consultation from your State government. A medical monitoring program should be established for the early detection and prevention of acute and chronic effects of exposure to nPB. The workers' physician(s) should be given information about the adverse health effects of exposure to nPB and the workers' potential for exposure.

Spray applications

. For spray applications (e.g., aerosols), consider your available options, and if using nPB, use sufficient ventilation to reduce exposure to maintain acceptable exposure levels.

. For ventilation, we recommend that you follow the design guidelines for ventilation in ACGIH's *Industrial Ventilation: A Manual of Recommended Practice* (ACGIH, 2002). In particular, the guidelines in Chapter 10.75 are appropriate for spray booths, and the **[*30198]** guidelines in Chapter 10.35 are appropriate for laboratory hoods.

. The ACGIH Ventilation Manual recommends a minimum flow rate of 150 cubic feet per minute (cfm) for each sq-ft of opening for a small booth with at least 4 sq-ft of open face area. This equates to an average face velocity of 150 ft/min. For a large booth, the recommended face velocity is 100 ft/min for walk-in booths and 100 to 150 ft/min for a large spray booth where the operator works outside. In general, the opening should be kept as small as possible to accommodate the work-pieces, generally 12 inches wider and taller

than the largest piece of work. If all spraying is not directed towards the back of the booth or the booth is too shallow for the size of the pieces being sprayed or if disruptive air currents are present at the face of the booth, a greater flow of air will be needed.

We note that these steps are useful for reducing exposure to any industrial solvent, and not just nPB.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action." It raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

In addition, EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in the document "Analysis of Economic Impacts of Proposed nPB Rule on Aerosols and Adhesives." A copy of the analysis is available in the docket for this action (Ref. EPA-HQ-OAR-2002-0064) and the analysis is briefly summarized here. EPA estimates the total costs of the proposed rule to between $ 38.6 and 46.4 million per year.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 2224.01.

If the provisions of this proposed rule become final (i.e., if the proposed regulatory language at the end of this document is finalized), there would be no new information collection burden. This proposed rule contains no new requirements for reporting or recordkeeping. OMB has previously approved the information collection requirements contained in the existing regulations in subpart G of 40 CFR part 82 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060-0226 (EPA ICR No. 1596.06). This ICR included five types of respondent reporting and record-keeping activities pursuant to SNAP regulations: Submission of a SNAP petition, filing a SNAP/Toxic Substance Control Act (TSCA) Addendum, notification for test marketing activity, record-keeping for substitutes acceptable subject to use restrictions, and record-keeping for small volume uses.

However, if EPA were to finalize the proposed alternate approach described in section VII.A of this preamble, users of nPB would have an information collection burden from exposure monitoring and recordkeeping. Under the proposed alternate approach, users of nPB would be required to monitor worker exposure initially and periodically (usually every 6 months) and keep records of these exposure data at the facility for at least three years from the date the samples were taken. This data is necessary to ensure that users of nPB are meeting the regulatory use conditions. If the data indicates that the use condition is not being met, it could be used by EPA or citizens in an enforcement action against the facility. These data would be considered available to the public and would not be considered confidential.

The estimated burden of recordkeeping for the entire regulated community under the proposed alternate approach is as much as $ 7.0 million and 13,170 hours per year. The estimated recordkeeping burden for a typical user is $ 96 and 0.18 hours per worker per monitoring event. We estimate approximately 1.9 monitoring events per year per worker, assuming that roughly 90% of exposed workers must be monitored every six months and 10% must be monitored once annually. We estimate that up to 35,000 workers would be monitored for exposure to nPB. Costs under the proposed alternate approach include the annual cost of purchasing passive organic exposure monitoring badges, the annual cost of services for analyzing the resulting exposure, and the annual cost of reviewing and filing the data up to 2 times per year.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review

instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA-HQ-OAR-2002-0064. Submit any comments related to the ICR for this proposed rule to EPA and OMB. See **Addresses** section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked "*Attention:* Desk Officer for EPA." Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after May 30, 2007, a comment to OMB is best assured of having its full effect if OMB receives it by June 29, 2007. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any **[*30199]** other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. However, the RFA also authorizes an agency to use alternate definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternate definition(s) in the **Federal Register** and taking comment. 5 U.S.C. 601(3)-(5). In addition, to establish an alternate small business definition, agencies must consult with SBA's Office of Advocacy.

EPA proposed an alternate definition for regulatory flexibility analyses under the RFA for rules related to the use of nPB as an alternative to ozone-depleting substances (ODS) in metals, precision, and electronics cleaning, adhesives, and aerosol solvents in the June 2003 NPRM (68 FR 33309, June 3, 2003). EPA established this final definition under section 601(3) of the RFA when we promulgated the final rule on the acceptable use of nPB in metals, precision, and electronics cleaning in the Rules and Regulations section of today's **Federal Register** . For purposes of assessing the economic impacts of this proposed rule on small entities, EPA defined "small business" as a small business with less than 500 employees, rather than use the individual SBA size standards for the numerous NAICS subsectors and codes. We believe that no small governments or small organizations are affected by this rule. EPA chose to use the alternate definition to simplify the economic analysis. This approach slightly reduced the number of small businesses included in our analysis and slightly increased the percentage of small businesses for whom the analysis indicated the use of nPB in accordance with this proposed rule may have an economically significant impact. Furthermore, this size standard was set by the Small Business Administration for all NAICS codes for businesses using nPB-based adhesives, one of the end uses that would be affected by this rule.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This rule proposes to list nPB as an unacceptable substitute for ODS in aerosols and adhesives. EPA has analyzed the economic impacts of switching from nPB to other alternative aerosol solvents or adhesives. EPA estimates that up to 3,380 small industrial end users currently use nPB in the end uses addressed by this proposed rule and thus

could be subject to the regulatory impacts of this rule. This number includes approximately 3,100 users of nPB-based aerosol solvents, and 280 users of nPB-based adhesives. Considering the regulatory impacts on adhesive and aerosol users that must switch to other alternatives, we found that up to 258 (8%) of small businesses would experience impacts of 1% or greater of annual sales and no small businesses would experience impacts of 3% or greater of annual sales. Based on the relatively small number and low percentage of small businesses that would experience significant economic impacts, EPA concludes that this rule would not have a significant economic impact on a substantial number of small entities.

In the case of coatings uses, our understanding is that only a single facility, the Lake City Army Ammunition Plant, is currently using coatings with nPB as the carrier solvent, and this facility could continue to use nPB following its current practices. Therefore, we consider there to be no economic impact of this rule on coatings users and have not done further analysis for this end use.

Types of businesses that would be subject to this proposed rule include:

. Manufacturers of computers and electronic equipment that clean with nPB cleaning solvents (NAICS subsector 334).

. Manufacturers of appliances, electrical equipment, and components that require oil, grease, and solder flux to be cleaned off (NAICS subsection 335).

. Manufacturers of transportation equipment, such as aerospace equipment that requires cleaning either in a tank or with aerosols, or aircraft seating, which is assembled using adhesives containing nPB as a carrier solvent; and ship or boat builders applying adhesives with nPB (NAICS subsector 336).

. Manufacturers of furniture, including various kinds of furniture with cushions and countertops assembled using adhesives containing nPB as a carrier solvent (NAICS subsector 337).

. Foam fabricators, who assemble foam cushions or sponges using adhesives containing nPB as a carrier solvent (NAICS code 326150).

In order to consider the resources that affected small businesses have available to operate and to respond to the proposed regulatory requirements, EPA compared the cost of meeting the proposed regulatory requirements to small businesses' annual sales. In our analysis for this proposed rule, we used the average value of shipments for the products manufactured by the end user as a proxy for sales or revenues, since these data are readily available from the U.S. Department of Commerce. The following tables display the average value of shipments for different sizes of business and different NAICS subsectors or codes in the affected industrial sectors. EPA then used data from these sources to determine the potential economic impacts of this proposed rule on small businesses.

Table 15.--Average Value of Shipments in NAICS Subsectors Using Aerosol Solvents, by Number of Employees at Business

Number of employees at business	Average value of shipments per business (] by NAICS subsector code		
	334, computer and electronic products	335, electrical equipment, appliance, and component mfg	336, transportation equipment
1 to 4 employees	345,007	315,772	412,460

Table 15.--Average Value of Shipments in NAICS Subsectors Using Aerosol Solvents, by Number of Employees at Business

Number of employees at business	Average value of shipments per business (] by NAICS subsector code		
	334, computer and electronic products	335, electrical equipment, appliance, and component mfg	336, transportation equipment
5 to 9 employees	1,317,238	1,243,065	1,414,384
10 to 19 employees	2,566,913	2,483,327	2,573,352
20 to 49 employees	5,672,245	5,389,945	5,738,739
50 to 99 employees	12,951,836	12,650,236	12,735,583
100 to 249 employees	31,258,875	31,290,638	34,256,544
250 to 499 employees	84,270,454	77,279,974	86,911,454
Avg. value ship small businesses in sub-sector	8,261,788	9,539,205	11,029,561
Avg. value ship all businesses in subsector	20,810,094	13,417,905	45,029,773
Avg. value shipments subset small businesses using nPB	11,246,045	12,066,562	13,422,547

Table 16.--Average Value of Shipments in NAICS Categories Using nPB as a Carrier Solvent in Adhesives, by Number of Employees at Business

Number of employees at business	Average value of shipments per small business () by NAICS sub sector				
	337121, upholster-ed household furniture	337110, wood kitchen cabinet and counter tops	326150, urethane and other foam products (except poly-styrene)	336360, motor vehicle seating and interior trim	337124, metal household furniture
1 to 4 employees	234,345	156,833	496,318	425,863	187,950
5 to 9 employees	963,021	622,744	1,305,183	1,728,132	903,393
10 to 19 employees	1,771,416	1,141,119	3,152,283	3,082,486	1,431,480
20 to 49 employees	3,653,623	2,619,197	6,615,331	5,508,370	3,538,684
50 to 99 employees	8,089,968	7,386,365	13,281,000	14,088,500	7,547,536
100 to 249 employees	17,502,175	17,151,091	31,524,872	44,310,286	19,821,719
250 to 499 employees	40,250,813	55,982,674	64,119,800	123,803,610	d(1)
Avg. Small Businesses in Sub sector	3,588,297	1,150,768	10,472,992	12,542,725	3,141,720
Avg. ALL Businesses in Sub sector	5,490,101	1,475,602	11,110,822	44,808,573	5,239,747
Avg. Subset Small Businesses using nPB	11,519,540	5,999,622	18,950,068	12,019,847	20,401,301

fn1 "d" designates "Data withheld to avoid disclosing data of individual companies; data are included in higher level totals." The average value of shipments for businesses estimates those values marked with "d," and thus may be overestimated or underestimated.

This proposed rule would list nPB as unacceptable for use in adhesives and aerosols. The available alternatives identified include adhesive formulations based on water, methylene chloride, or flammable solvents such as acetone and aerosol formulations of flammable solvents, combustible solvents, blends of trans-dichloroethylene and HFEs or HFCs, and HCFC-225ca/cb. We considered various aspects of the cost of switching to other alternatives, including the cost of meeting OSHA requirements and the cost of the alternative adhesive. We specifically request public comment on the assumptions and costs used in EPA's analysis (US EPA, 2007).

We estimate that up to 9 small businesses using nPB-based adhesives, or roughly 3% of the 280 or so small businesses that use nPB-based adhesives, would experience a cost increase (i.e., an impact) of greater than 1.0% of annual sales, and no small businesses would experience an impact of greater than 3% of annual sales if this proposed rule became final. For small businesses using nPB-based aerosols, we estimate that approximately 249 would experience a cost increase of greater than 1.0% of annual sales. This equates to roughly 8% of the 3100 or so small businesses currently using nPB-based aerosol solvents. No small businesses using aerosols would experience an impact of greater than 3% of annual sales. Approximately eight percent of all 3380 or so small businesses choosing to use nPB in these end uses would experience an impact of greater than 1.0% of annual sales and no small businesses would experience an impact of greater than 3.0% of annual sales. Because of the small total number and small percentage of affected businesses that would experience an impact of greater than either 1.0% or 3.0% of annual sales, EPA does not consider this proposed rule to have a significant economic impact on a substantial number of small businesses.

We also analyzed the potential small business impacts of the proposed alternate approach. Under the proposed alternate approach, users would have to: (1) Meet an exposure level of 20 ppm on an eight-hour time-weighted average, (2) monitor workers' exposure to nPB using a personal breathing zone sampler on an eight-hour time-weighted average initially and periodically (every 6 months or longer, depending on the concentration during initial monitoring), and (3) keep records of the worker exposure data on site at the facility for at least three years from the date of the measurement. We assume that the cost of following the proposed alternate approach is the cost of installing ventilation for aerosols and adhesives or emission controls for solvent cleaning, the cost of using personal protective equipment, and the cost of monitoring worker exposure. Approximately 67 to 387 aerosol solvent users (2 to 13 percent), 25 to 54 adhesive users (9 to 19 percent), and 2.6 to 12.6 percent of all 3380 or so small businesses would experience impacts of greater than 1% of annual sales if they chose to use nPB subject to the proposed use conditions rather than switching to another ODS substitute. **[*30201]** Four to nine users of nPB-based adhesives, or less than 1% of all small businesses affected by this proposal, would experience impacts of 3% or greater of annual sales under the proposed alternate approach. Based on this analysis, the proposed alternate approach would not create a significant adverse economic impact on a substantial number of small entities.

Although this proposed rule would not have a significant economic impact on a substantial number of small entities if it became final, EPA nonetheless has tried to reduce the impact of this rule on small entities. Before selecting preferred the regulatory option in this proposed rule, we considered a number of regulatory options, such as:

. Placing a narrowed use limit on the use of nPB in adhesives and aerosols that would allow its use only in those cases where alternatives are technically infeasible due to performance or safety issues. This would have required testing, recordkeeping, and some installation of capital equipment.

. Requiring that when nPB is used in adhesives or aerosols, it must be used with local ventilation equipment and personal protective equipment. This would have required further installation of capital equipment, without necessarily protecting workers as thoroughly as a required acceptable exposure limit or requiring a switch to another alternative.

. Prohibiting the use of nPB in all end uses.

. Retaining the previously proposed requirement for a limit on iPB content in nPB formulations.

The costs of a number of these options are included in EPA's analysis (US EPA, 2006; U.S. EPA, 2007).

In developing our regulatory options, we considered information we learned from contacting small businesses using or selling nPB. EPA staff visited the site of a small business using nPB for cleaning electronics. We contacted several fabricators of foam cushions that have used adhesives containing nPB. We participated in meetings with a number of adhesive manufacturers and users of adhesives in furniture construction. We developed a fact sheet and updated our program Web site to inform small businesses about the proposed rule and to request their comments.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $ 100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $ 100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. This proposed rule does not affect State, local, or tribal governments. The enforceable requirements of the rule for the private sector affect a number of end users in manufacturing. The estimated cost of the proposed requirements for the private sector is approximately $ 38.6 to 46.4 million per year, and the proposed alternate approach would cost the private sector approximately $ 42.3 to 67.5 million per year. Therefore, the impact of this rule on the private sector is less than $ 100 million per year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. This regulation applies directly to facilities that use these substances and not to governmental entities.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the National government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This regulation applies directly to facilities that use these substances and not to governmental entities. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

This proposed rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the **[*30202]** Federal government and Indian tribes, as specified in Executive Order 13175.

This proposed rule would not significantly or uniquely affect the communities of Indian tribal governments, because this regulation applies directly to facilities that use these substances and not to governmental entities. Thus, Executive Order 13175 does not apply to this proposed rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The exposure limits and acceptability listings in this proposed rule apply to the workplace. These are areas where we expect adults are more likely to be present than children, and thus, the agents do not put children at risk disproportionately.

The public is invited to submit or identify peer-reviewed studies and data, of which the agency may not be aware, that assessed results of early life exposure to nPB.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action would impact manufacturing of various metal, electronic, medical, and optical products cleaned with solvents containing nPB and products made with adhesives containing nPB. Further, we have concluded that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involved technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards. We note that the American Conference of Governmental Industrial Hygienists (ACGIH), although it sets voluntary standards, is not a voluntary consensus standards body. Therefore, use of an acceptable exposure limit from the ACGIH is not subject to the NTTAA.

XII. References

The documents below are referenced in the preamble. All documents are located in the Air Docket at the address listed in section I.B.1 at the beginning of this document. Unless specified otherwise, all documents are available electronically through the Federal Docket Management System, Docket # EPA-HQ-OAR-2002-0064. Some specific items are available only in hard copy in dockets A-2001-07 or A-92-42 (legacy docket numbers for SNAP nPB rule and for SNAP program and submissions). Numbers listed after the reference indicate the docket and item numbers.

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List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Dated: May 15, 2007.

Stephen L. Johnson,

Administrator.

For the reasons set out in the preamble, 40 CFR part 82 is proposed to be amended as follows:

PART 82--PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for Part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671--7671q.

2. Subpart G is amended by adding Appendix S to read as follows:

Subpart G--Significant New Alternatives Policy Program

* * * * *

Appendix S to Subpart G--Substitutes Subject to Use Restrictions and Unacceptable Substitutes

Listed in the May 30, 2007 final rule.

Aerosols--Unacceptable Substitutes

End use	Substitute	Decision	Further information
Aerosol solvents	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Unacceptable	EPA finds unacceptable risks to human health in this end use compared to other available alternatives. nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.

Adhesives, Coatings, and Inks--Substitutes That Are Acceptable Subject to Use Conditions

End use	Substitute	Decision	Use conditions	Further information
Coatings	n-propyl bromide (nPB) as a substitute for methyl chloroform, CFC-113, and HCFC-141b	Acceptable subject to use conditions	Use is limited to coatings at facilities that, as of May 30, 2007, have provided EPA information demonstrat-ing acceptable workplace exposures	EPA recommends the use of personal protective equipment, including chemical goggles, flexible laminate protective gloves and chemical-resistant clothing. EPA expects that all users of nPB would comply with any final Permissible Exposure Limit that the Occupational Safety and Health Administration issues in the future under 42

Adhesives, Coatings, and Inks--Substitutes That Are Acceptable Subject to Use Conditions

End use	Substitute	Decision	Use conditions	Further information
				U.S.C. 7610(a). nPB, also known as 1-brompropane, is Number 106-94-5 in the CAS Registry.

As of May 30, 2007, the Lake City Army Ammunition Plant is the only facility using nPB in coatings that has provided information to EPA that meets this condition.

Adhesives, Coatings, and Inks--Unacceptable Substitutes

End use	Substitute	Decision	Further information
Adhesives	n-propyl bromide (nPB) as a substitute for CFC-113, HCFC-141b, and methyl chloroform	Unacceptable	EPA finds unacceptable risks to human health in this end use compared to other available alternatives. nPB, also known as 1-bromopropane, is Number 106-94-5 in the CAS Registry.

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The Effect of the Proposed USEPA Recommendation of a 25 ppm Workplace Exposure Level on the n propyl bromide Industry

Background on the n Propyl Bromide (nPB) Industry

At present, nPB is used as a solvent in the precision cleaning sector (industrial vapor degreasing, ultrasonic and cold wipe cleaning), as a carrier in the adhesive, carriers and ink sector (as a dilutant for the application of adhesives, paint and polymer coatings) and as a pharmaceutical intermediary in the production of ibuprofen and other drugs. A USEPA SNAP ruling will apply only to the precision cleaning and adhesive, coatings and inks sectors.

Current estimates see the total halogenated solvent market place in the United States to be approximately 808 million pounds per annum. nPB based solvents are estimated to have a market share equal to between ½ to 1% of the total U.S. halogenated solvent market.

Benefits of nPB Based Solvents

Since the phase out of 1,1,1 Trichloroethane ("TCA") and HCFC-141b ("141b") by the USEPA SNAP program to meet the mandate of the Montreal Protocol, nPB is the only viable new alternative solvent developed for vapor degreasing, ultrasonic cleaning and carrier applications that is economically viable for small business use. The physical characteristics and cleaning performance of nPB solvents make them ideal replacements for TCA and 141b, and they are in many respects superior to other halogenated solvents. As a non-flammable, azeotropic, non-ozone depleting, non-global warming, high solvency, high metal and component compatible solvent, nPB is a very rare phenomenon. nPB's unique role is that it can do almost exactly what TCA and 141b did for industry in the most sensitive and critical manufacturing applications such as printed circuit boards and military and aerospace components. NPB achieves these results using existing equipment; large capital investments are unnecessary in order to obtain the benefits of nPB solvents.

Future Expected Economic Benefits

The nPB which is currently available in the marketplace is manufactured using the excess manufacturing capacity of existing equipment by companies that are already in the business of manufacturing

brominated products. Modest investments of capital in plant and equipment can purchase efficient additional manufacturing capacity in the U.S. and elemental bromine is readily available. Currently, the market for nPB as an unstable raw material has not achieved sufficient quantities to justify investment in new manufacturing capacity. As demand increase and reach appropriate economies of scale, we expect a larger portion of the unstable raw nPB may be manufactured by small U.S. businesses they are the primary manufacturer of nPB solvents. Vertical integration is likely to occur as producers of stabilized nPB solvents begin to produce raw nPB for use in their solvents.

Overview of the Current nPB Industry

The nPB industry is comprised of four distinct levels of participation:

1) Production of nPB as an unstable raw material;
2) Conversion of nPB from an unstable raw material to a stabilized industrial solvent and support of its use by industry;
3) Distributors of the stabilized nPB industrial solvents and re-labelers
4) End users

Production of nPB as an unstable raw material

Approximately 15% of the unstabilized raw material nPB is manufactured by domestic U.S. producers which are small businesses. Approximately 60% of the nPB has been supplied by Ameribrom, the U.S. arm of DSBG, an Israeli company. Small amounts, about 5%, of nPB are produced by Albemarle (a large bromine U.S. based bromine product company) in Europe with the remainder imported from China.

Raw material producers merely provide a indistinguishable commodity chemical which has limited or no functional value in the industrial marketplace. NPB, in its neat state, cannot by itself be used as an industrial solvent; it requires stabilization against the creation of acid and corrosion of white and ferrous metals as well as a technical support infrastructure which can address the myriad of different specific industrial uses. Raw material producers do not provide any of the required stabilization or support.

Production of Stabilized nPB Based Industrial Solvents

Raw nPB is manufactured into a usable product by the addition of other chemical compounds which stabilize the nPB. The discovery of nPB's potential as a useful industrial solvent was made by persons independent of any affiliation with large, well known chemical companies. The research and development of nPB into a useful solvent was completed through the use of independent testing laboratories funded by individuals risking personal and retirement savings.
The R&D leading to the methods of stabilization are the subject of over 10 patents owned by small U.S. businesses. These patents, and therefore the bulk of the nPB market, are owned by small businesses which manufacture over 90% of the nPB based solvents sold in the U.S.
Once formulated for solvent use, the product requires significant expertise in the appropriate maintenance in order to be used as an industrial solvent.

Five major nPB solvent producers, all of which are small businesses, are located throughout the U.S.; in Illinois, Ohio, New Jersey, Oklahoma and Florida. As discussed above, one company manufactures both the raw nPB and the solvent in Europe (the only nPB solvent manufacturer not classified as a small business); it is estimated this company has a 5% share of the total nPB market.

There is a clear distinction between unstable raw nPB material producers and actual manufacturers of stabilized nPB industrial solvents. An automobile manufacturer does not produce the raw steel, plastic and rubber which goes into the manufacture of a car or truck but is logically understood to be the manufacturer of the vehicle. In the same way, these six companies are the *true* manufacturers - the primary creators - of nPB industrial solvents as only they produce the useful end product for sale in the industrial marketplace.

The manufacturing process adds other chemical compounds, between 5% to 25% of the finished product, to raw nPB to counteract the creation of acid, corrosion of ferrous and white metals and as formulates for specific cleaning processes. These chemical compounds making up the various stabilization packages are purchased as commodity chemicals on the open market from other large and small businesses alike. The manufacturing process of stabilizing nPB and providing the technical support for its use adds 100% to 400% to the value of the indistinguishable raw commodity component.

Distribution and Re-labeling of nPB Based Solvents

The next level in the nPB industry is that of distributors and re-labelers. Although each solvent manufacturing company sells directly to end users, all also use a network of distributors to market their products. There are over 50 separate companies distributing and supporting the use of the nPB solvents manufactured by the five major manufacturers. It is also estimated that there are over 60 additional companies which purchase finished product from the five major nPB solvent manufacturers, re-label and market the product as their own proprietary brand. Finally, there are 30 or more independent sales representation firms selling products produced by the major manufacturers. The vast majority of the companies at the distribution and re-labeling level are small businesses. Five of the six major nPB solvent manufacturers market their products internationally.

End Users

We estimate that approximately 2,500 U.S. companies and government agencies are end users of nPB based solvents in precision cleaning or adhesive carrier applications, including the DOD, NASA and the Department of Energy. Of the 2,500 end users, well over 2,000 are small businesses. Most large companies, such as Boeing in the aerospace industry, have been reluctant to use nPB products because they lack final USEPA SNAP approval. This view was confirmed and discussed by competing firms selling non-nPB solvents in the June, 2002 issue of CleanTech magazine (attached).

The nPB Industry's Place in the Industrial Cleaning Market

There are essentially three solvent options available in the industrial marketplace. All three options, given *current* workplace exposure guidelines, can be used in existing equipment without expensive capital outlays for improvements or modifications.

The traditional chlorinated compounds, trichloroethylene ("TCE") and perchloroethylene ("PERC"), are one of industry's options for cleaning applications. Methylene chloride, another traditional chlorinated solvent, is not a cleaning option for performance reasons, but is used as a carrier in the adhesive sector. All the traditional chlorinated compounds are non-flammable, have proven use capabilities and unique physical characteristics. However, all three chlorinated compounds are considered to be human carcinogens by the USEPA and/or OSHA. TCE and PERC are sold as commodities priced at or about $500.00 per 55 gallon drum.

Another solvent option at the opposite end of the price scale are what are termed "designer solvents". Most, if not all of these compounds do not exist in nature and were developed specifically as replacements for ozone destroying compounds. These products are currently considered to be relatively non-toxic, although toxicological testing of these materials has not been as extensive as that of nPB. Typically, these compounds have only a fraction of the cleaning capability of the traditional chlorinated solvents and are extremely expensive, selling for $9,000.00 to $13,000 per 55 gallon drum. In many cases, these solvents are mixed with existing chlorinated solvents for improved cleaning capability with little reduction in price.

The last solvent option is the use of nPB based solvents. The physical characteristics of nPB based solvents closely match that of the most popular banned solvent, 1,1,1-trichloroethane. NPB solvents, depending on the grade of nPB used, are priced between $1,500.00 to $2,400.00 per 55 gallon drum. NPB based solvents are the only solvents in a price range between the cheap chlorinated solvents and overly expensive designer solvents. Our continued presence in the market shows that end users will pay a premium (the difference in price between nPB and the cheaper chlorinated solvents) for a non-carcinogenic solvent which they perceive, due to WEL's, are of otherwise equal safety but rarely opt for the expensive designer solvents for obvious economic reasons.

The products used in both of the first two options are manufactured by the same large, multi-national chemical companies. Since the chlorinated solvents have been used for years, distribution and sales networks are mature with little room for new entrants at the manufacturing or distribution level. The newer designer solvents have for the most part been marketed through that existing distribution network. nPB based solvents are the only products with which small businesses can participate in the solvent cleaning marketplace. U.S. and foreign patents protect the stabilizing packages which make nPB a useful solvent and therefore protect the nPB industry from being taken over by large chemical companies in the marketplace.

No Industry Failure to Protect Worker Health

Since a Petition for SNAP approval was filed in 1995, the nPB industry has cooperated at every level

with the requests of the USEPA. The industry has invested millions of dollars in atmospheric studies, animal testing and scientific interpretations of the resulting data, including performing expensive animal testing which the USEPA has not required for any other chemical reviewed under SNAP. In addition, the industry has provided the National Toxicology Project with all available toxicological data, has cooperated with the NTP review of nPB and supports the NTP's proposed animal testing. Industry participants have also participated in and otherwise assisted NIOSH with human workplace exposure studies.

Since 1998, the industry proposed and successfully worked to promulgate an ASTM standard (ASTM 6368) regarding contamination of raw nPB by 2-bromopropane (a suspected toxic compound) limiting 2-bromopropane contamination to one tenth of one percent of the final weight of nPB used to produce industrial solvents. When the final ASTM standard was promulgated in early 2000, the nPB solvent manufacturers implemented the ASTM standard practically overnight. It is now a market demand that nPB solvents meet the ASTM standard. Since the promulgation of the ASTM standard, the industry has continued its research to develop modifications in nPB production, successfully limiting 2-bromopropane contamination to current levels of .05% or less.

All six major nPB solvent manufacturers have had customer support programs in place since initiating solvent sales which advise end users on solvent and equipment issues. At the heart of these programs is the limitation of solvent use, which results not only in an easily quantified benefit for the end users in cost savings but also in the protection of worker health and safety.

Disposal of spent solvent is another important issue of product stewardship which nPB solvent manufacturers have addressed since the beginning of nPB solvent sales. Spent nPB solvents can be reclaimed, sold and reused in the marketplace. Typically, solvent manufacturers have in place and encourage participation in disposal programs which minimize disposal cost for end users and provide manufacturers with an economical source of reclaimed product.

The nPB industry has based its programs and recommendations on the advice of independent world renown scientists, not staff employees. The nPB industry has voluntarily taken these steps without intervention or regulation by any governmental agency and has had these programs in place while the USEPA's review dragged on for nearly seven years. In fact, the lack of any substantive action by the USEPA for nearly seven years supports our view that no emergency health problem exists which demands any action, let alone extraordinary action, from the USEPA.

Other Practical Considerations

The following considerations are set forth as background and will be discussed in context below.

Market Understanding of WEL

It is a fact of life that industrial chemical users equate the workplace exposure level of a chemical directly with its perceived safety - the lower the number, the less safe it is to use. Our competition echoes this fact in a recent edition of CleanTech, a trade magazine, where David Ferguson, national

sales manager for AGA Chemical (a multinational corporation selling a competing non-nPB product) states that "a number of 100 or higher is considered safe, and products with a number below 100 often get a second look when judging their safety."[1]

Exposure Levels of Competing Solvents

Below is a list of SNAP approved non-flammable compounds in actual use in the in the precision cleaning sector and their associated OSHA PELs or USEPA approved manufacturer's WEL:

trichloroethylene - OSHA PEL 100 ppm
perchloroethylene - OSHA PEL 100 ppm
methylene chloride - OSHA PEL 25 ppm
1,2, trans-dichloroethylene - OSHA PEL 200 ppm
HCFC-225 - manufacturer's suggested WEL approved by USEPA 100 ppm (recently raised from 25 ppm)
HFE 7100 - manufacturer's suggested WEL approved by USEPA 750 ppm
HCFC-4310-mee - manufacturer's suggested WEL approved by USEPA 200 ppm
HFE 7200 - manufacturer's suggested WEL approved by USEPA 200 ppm

Carcinogenicity

The USEPA and OSHA have long held the default view that there is no safe exposure level to a carcinogen. Carcinogenicity is the basis for the 25 ppm OSHA PEL for methylene chloride. At present, the USEPA and the IARC considers TCE to be a probable human carcinogen and PERC to be a suspected human carcinogen. On the other hand, the USEPA, its consultant ICF Consulting and industry experts all agree that nPB is not likely to be a carcinogen.

No Review of Toxicity for Aqueous Compounds

There is little doubt that the USEPA prefers aqueous cleaning systems over solvent cleaning systems. Aqueous cleaning systems are those where cleaning agents are dissolved in water. Under SNAP, any cleaning chemical which can be dissolved in water can immediately proclaim itself as SNAP approved without so much as filing a Petition for Approval. Therefore, the USEPA has not in the past and does not now review the toxicity or the atmospheric effects of any aqueous compounds in the marketplace and yet does not object to these compounds being advertised as SNAP approved.

No Animal or Human Data Show Adverse Effects of Exposure at 100 ppm

No adverse effect of exposure to nPB in animals or humans has ever been found at or below 100 ppm. In fact, NIOSH studies have shown that the first effect found on workers is the onset of headaches at an exposure level of above 180 ppm. The first significant reproductive effect found in rats was decreased sperm motility at 500 ppm. The nPB solvent manufacturers utilizing the best peer reviewed science available in order to provide an adequate margin of safety, have reached a consensus that 100 ppm is protective of human health.

Analysis of the Impact of a 25 ppm Exposure Level for nPB

A recommendation by the USEPA of 25 ppm will be understood by the market that, for whatever reason, nPB is four times as dangerous as TCE. Economic realities are clear that users will not pay a premium for a product they perceive as less safe when other cheaper products exist which are perceived as safer. Nor will economic realities allow companies to invest in expensive control technologies in order to use a product perceived to be more dangerous when they can purchase a cheaper product which can be used in existing equipment without the necessity of installing expensive additional control measures. Likewise, users will continue to use and/or likely switch to cheap carcinogenic compounds because the only other choice for solvent users are the designer solvents which are 15 to 20 times more expensive and have less cleaning ability.

Again, our competition describes the consequences in the marketplace. In CleanTech, Dave Ferguson of AGA states that if the EPA puts nPB on a lower level in terms of toxicity, "people are going to go to trichlor[ethylene]". In the cleaning sector, if nPB is tainted as a more dangerous chemical, switching to or continuing the use of lower cost chlorinated solvents is the least cost approach for all businesses, *large and small, even though the USEPA believes TCE is a human carcinogen and that there is no safe level of exposure to a carcinogen.* The same is true in adhesive carrier applications, where methylene chloride would be the least cost approach because it would be viewed as equally dangerous based on WELs, but five to six times less expensive. There is no economic incentive within the rule or the marketplace for end users to invest large sums in capital equipment for control technologies to achieve an artificially low exposure level or to incur increased production costs of up to 15% to 21% for designer solvents.

A workplace exposure of 25 ppm means U.S. industry is essentially deprived of nPB and the small businesses involved in the production, manufacture and distribution of nPB solvents are devastated. The economic effect will likely cause a significant reduction in the number of nPB solvent manufacturers which will simply go out of business. Ripple effects will be felt up the chain where raw material producers will cut supply to coincide with decreased demand. Since less production negates any economies of scale, it is assured that raw material prices will increase. Effects will be felt down the chain, where the distributors, re-labelers and independent representatives will lose an entire product line with little or no options as replacements. Higher raw material prices charged for the few companies remaining in the nPB business will cause further price increases to end users and further erode sales of nPB.

As a result, the regulation will protect only the monopoly of the large business manufacturers of halogenated/designer solvents. This severe regulation will deprive industry of an affordable alternative for industrial vapor degreasing cleaning and carrier applications and will also force small businesses which cannot afford to use costly designer solvents to use suspected carcinogens, relocate overseas or cease to manufacture, thus shifting production to larger businesses that can afford the significant capital investment of new equipment or accept a 15 to 21% increase in production cleaning costs.

In many cases, small business do not have cash reserves nor ready access to loaned capital in which to

fund major equipment purchases. In the same vein, the extra production costs caused by more expensive solvents or capital improvements will cause an increase in cost per production unit far above that of a large multi-national company. Also, it will be necessary for small businesses to use what cash and credit they do have to fund the higher costs of production, instead of using those resources for expansion, new product development or worker benefits. In any case, small businesses are not on a level playing field with large corporations.

The USEPA's Recommendation Will Force Manufacturers to Use Carcinogens

TCE, a solvent determined to be likely to cause cancer in humans, currently has an OSHA PEL of 100 ppm. As we have discussed above, with a USEPA recommendation of 25 ppm manufacturers will perceive that nPB is less safe and, given that TCE is only 25% the cost of nPB, will use TCE because it is the least cost approach. Thus, setting an artificially low workplace exposure level which has no scientific basis or economic benefit to workers will actually lead more individuals being exposed to cancer risks and the costs associated with those cancer risks.

A 100 ppm exposure level gives a five fold margin of safety from where effects were seen and a nearly three fold margin from the established USEPA bench mark dose low ("BMDL") of 281 ppm, which is the equivalent of a no effect level for sensitive populations. The risk comparison here is between exposure to a compound (nPB) showing effects on sperm motility in rats (at 500 ppm) at a level that includes a three to five fold safety margin versus exposure to compounds which USEPA policy states have *no* safe exposure level because they are carcinogens.

The Aqueous Cleaning Option - Rarely an Option At All

The USEPA also suggests that manufacturers have an option to switch to aqueous cleaning instead of defaulting to the carcinogenic solvent. SNAP allows any aqueous based cleaning system to market itself as SNAP approved without any environmental or toxicological study whatsoever even though toxic chemicals are mixed with water to perform cleaning operations. Unfortunately, using regulatory roadblocks to prevent the use of nPB will not force manufactures to convert to aqueous cleaning because such a conversion is not cost effective.

Aqueous cleaning is not effective in many precision cleaning applications. In many instances, it is impossible to forecast whether the aqueous system will actually work in a specific cleaning application until it is fully installed and operational. Thus, there is a higher risk of capital loss or additional capital investment necessary in installing an aqueous system.

Aqueous cleaning equipment is approximately three to eight times the cost of equivalent solvent cleaning equipment. The square footage footprint required to install such equipment can be as much as twenty times that for solvent cleaning equipment. Additionally, costly water treatment facilities are typically required to treat the discharge. Another recent CleanTech article describes an aqueous system user's investment of $800,000.00 (including a new building to house the equipment) for waste water treatment equipment to deal with excess chemical use and disposal issues. Industry also must deal with increased production time, increased energy costs, substrate incompatibility (i.e. rusting of metal parts) and

increased failure rate inherent in aqueous systems.

It is also well known that aqueous systems require far more electrical energy to operate than solvent cleaning equipment. In areas where that energy is provided by coal burning power stations, aqueous cleaning contributes directly to global warming far more than solvent cleaning.

Finally, manufacturers are unlikely to scrap solvent cleaning equipment, invest thousands to hundreds of thousands of dollars per replaced machine and use a method which is less effective when they can simply use other solvents in existing equipment and bypass a huge capital investment.

Legal Issues Arising from a USEPA Recommendation for a Workplace Exposure Level

The USEPA has No Authority to Speak on Issues Regarding Workplace Exposure Limits

Under SNAP, the USEPA has the authority to protect human health and the environment from the deleterious effects of stratospheric ozone depletion. The Clean Air Act by its internal operation does not preempt the authority or responsibilities of any other Federal agency under any other statute. OSHA has been charged by Congress to regulate safety in the workplace including workplace exposure guidelines. Therefore, regulation of the workplace is outside the authority of the USEPA under the Clean Air Act.

USEPA Has No Published Rules, Guidelines, Practices or Procedures for Recommending WELs

The criteria to be used by OSHA are set forth in statute and regulations and have been the subject of extensive judicial scrutiny to ensure fair and appropriate application of the law. In contrast, USEPA has published no rules, procedures, guidelines or targets to be used to establish a workplace exposure recommendation. The U.S. Supreme Court has held that OSHA must first make a finding that a workplace in question is not safe before promulgating any standard. The court went on to state that "safe" is not the equivalent of "risk-free" and that a workplace can hardly be considered "unsafe" unless it threatens the workers with a "significant" risk of harm.

The EPA, rejecting the standards required for OSHA, has chosen a level that is not only safe but well below the level at which leading independent scientific experts believe is appropriate to protect nearly all workers. In fact, the workplace exposure level is so low that the EPA can only justify its actions by utilizing arbitrary safety factors to extrapolate additional safety precautions necessary to safely protect children, infirm and elderly. Applying a safety factor for sensitive populations which are either prohibited by law from the workplace or not expected to be in the workplace is not justifiable. This approach is not only inappropriate as per the Supreme Court's standard, but will either force end users to fund capital improvements which will have no corresponding economic or health benefit whatsoever or, most likely cause end users to switch to alternative solvents which are consider by the USEPA to be "highly likely to cause cancer in humans."

Problems with Future OSHA Regulation

A recommendation of a workplace exposure level is likely to cause confusion in the market place. Further, it is likely that OSHA will be unduly influenced by another Federal agency's prior pronouncement on the issue; after all, at minimum, OSHA will be called on to explain why it does not agree with another Federal agency's view on the issue.

Budgetary Issues

Both the Clean Air Act and the Occupational Safety and Health Act provide mechanisms to guard against regulatory overlap and duplication. It is unreasonable then to assume that Congress would grant duplicative authority to two distinct agencies and also fund both agencies' regulation of the same arena. Therefore, it must be questioned as to whether USEPA funds are being spent by the Agency in a way that is consistent with the appropriation of funds by Congress.

International Trade Issues

A large portion of the raw nPB used to manufacture industrial solvents is imported into the United States from Israel. In the past, it was common to see governmental regulations using health and safety as a basis be used as veiled attempts to limit imports of foreign products into a country where overt tariffs or other trade actions were not feasible. Therefore, it is a fundamental aspect of current international trade agreements that such regulations which are not based on the best available science are deemed technical trade barriers.

Peer reviewed science by internationally respected toxicologists support the industries consensus of a 100 ppm workplace exposure level. Even seen in a light most advantageous to the USEPA, the Agency, in ignoring these peer reviewed assessments and basing their recommendation on one error ridden consultant's report, treads dangerously close to crossing the line of being a technical trade barrier. The Israeli government has stated to the USEPA that it is prepared to protect access to U.S. markets for its products based on international trade agreements.

There is no benefit to be gained by a recommendation from an agency with no statutory authority to speak in the area, no experience in this regulatory arena operating without any accountability, which is clearly based on policy instead of science opening trade issues with a staunch ally. Additionally, instead of protecting U.S. business interests, in this case, those interests will be harmed to a greater extent than will be the foreign manufacturer's.

Conclusion

Since there is no existing emergency health issue and the nPB industry has not failed to protect worker health, but rather has acted as a responsible corporate citizen in its marketing and stewardship of nPB based products, we believe that the nPB industry should be permitted to regulate itself as to the question of a recommended workplace exposure level until such time as OSHA acts just as the USEPA has allowed the large, multi-national chemical companies to self regulate on this issue.

Our request is appropriate because it is consistent with the regulatory scheme of the Occupational Safety and Health Act which imposes the duty on every employer to maintain a safe workplace environment. Our request is also appropriate because it is consistent with prior rulings and recommendations in the precision cleaning and adhesive, coatings and inks sectors under SNAP, is founded on sound, independent, peer reviewed scientific assessments which meet the requirements of the OMB and USEPA guidelines, is in keeping with the intent of the House of Representatives as expressed in H.R. 64, satisfies all parity concerns without advantage to nPB or detriment to other competitive products and is the most cost effective solution which accomplishes the objective of protecting worker safety without destroying the nPB-based solvent industry and its customers and suppliers.

Endnotes

1. *Regulatory Watch*. CleanTech Vol. 2 No. 6 Witter Publishing. June, 2002

Follow up telephone calls–nPB use in adhesives

Date: October 1, 2001

From: Margaret Sheppard, EPA/SNAP program

To: Fred Walnut, John Poinecka, Ron Sendeling, TACC Adhesives
(Fred's number: 781-681-0472)

Q: In what applications do companies use nPB-based adhesives? Is it used for upholstered furniture manufacturing, motor vehicle seating, aircraft seating?

A: There are two main applications: foam fabrication and high pressure laminants (not veneers). Companies that use nPB-based adhesives for laminants use it for desks and countertops. There are also uses in auto trim and post forming (premade countertops).

Basically, companies use nPB-based adhesives in preference to adhesives with methylene chloride. So, nPB could be used in the same places as meth: for high pressure laminant, auto trim, countertops, upholstery, and especially for foam fabrication.

Q: So, would you say that nPB is used in mobile homes, pre-fabricated wook bulidings, wood kitchen cabinet and countertop manufacturing?

A: That sounds right. It might also be used in recreational vehicles. You might check with Kim Thiell in RTP, who works on MACT standards.

Q: Do the companies using nPB tend to be smaller companies?

A: Yes.

Q: When did nPB first start being used?

A: We started using 1,1,1 [trichloroethane]. Next we switched to methylen chloride. For a while, companies were starting to use CBM [chlorobromomethane]. Then it was taken off the market. nPB started being used widely recently, after 1999.

nPB is a VOC, unlike methylene chloride. Therefore, nPB can't be used in California or the Ozone Transport Region.

Q: How many distributors would be affected by regulations on nPB?

A: Tulstar is the main distributor to the adhesive manufacturers. Great Lakes also used to

distribute nPB for adhesives. There are thousands of distributors out there.

Q: What is the number or percentage of companies using nPB-based adhesives in different business categories?

A: We can't really say.

Q: What is the size of the entire market?

A: Foam fabrication is roughly $800 million/year, served by a couple of adhesive companies. All other uses together are $800 million/year, served by one major adhesive company. The other main use besides foam fabrication is in building products, like prefab housing or counter tops.

Q: What's a typical cost for nPB before it's put into adhesives?

A: $1.10-$1.50 per pound.

The representatives from TACC Adhesives expressed concern that EPA could rule that nPB is unacceptable. I responded that this was not necessarily the case, and we were considering several different regulatory options. In particular, EPA is trying to take into account the possible impacts on small businesses, as required by law.

Q: What do you think would be the impact if nPB were to be unacceptable?

A: If nPB went away, millions of dollars would be lost. There are as many as 5000 small distributors that would be affected.

Big facilities have more options. It is easier for them to use water-borne adhesives. However, it takes longer for those adhesives to dry. A company could use a heater.

Small companies might have as few as one to five people actually spraying adhesive. They need to use solvent because it dries more quickly (5 min. vs. 10-15 min. for water). Switching to flammable adhesives is a minimal cost.

Water-borne adhesives can be more expensive. First, there'd by a need to switch to the guns, at $1000. Then there would be capital expenses for dryers, fans, etc. to aid evaporation, on the order of $6000-8000. And then their utilities would be higher for running that equipment.

We think that water-based adhesives don't work well on countertops. There's just no place for the water to go.

Q: What types of regulatory options are less likely to have a financial impact on small businesses?
-affecting formulation/mfg (e.g., limit impurities)

-technology-based (for controls)
-performance-based (aiming for certain limits)
-ban (“unacceptable”)

A: We’d have to think about that.

Q: Tell me about TACC Adhesives. Are you a small business?

A: We employ roughly 300 people, so we’re pretty big.

We specialize in adhesives and sealants. We sell both aerosol and contact adhesives, especially for building adhesives and auto uses. Our products include flammable, non-flammable, and water-borne adhesives.

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Congress of the United States
House of Representatives
Washington, DC 20515-3006

April 10, 2002

The Honorable Christine Todd Whitman
Administrator
Environmental Protection Agency
Ariel Rios Federal Building
1200 Pennsylvania Avenue, N.W.
Room 3000
Washington, D.C. 20004

Dear Administrator Whitman:

I am writing to you to express my concern regarding EPA treatment of Enviro Tech International, Inc., and the Agency's ongoing rule making on its petition for n Propyl Bromide (nPB) under the SNAP program. After six years without resolution, and over one year since the EPA again publicly stated it would propose nPB as acceptable, the Agency has yet to publish its rule. It is my understanding that EPA's failure to issue its ruling is in order to include a *non-binding, unenforceable recommendation* regarding workplace exposure levels (WEL). Scientific assessments reveal that there is nothing so unusual about this compound that warrants such delay. In addition, both government and industry have incurred great expense due to this postponement for a mere recommendation which is the purview of OSHA, and outside EPA's authority. I am also concerned that worker safety may be compromised where industrial users continue to use alternative cleaning agents, which are known and suspected carcinogens while waiting for SNAP approval of nPB.

I am curious why the SNAP process has held nPB to a much higher standard than any other compound, including mandatory animal testing using unique protocols, as well as the application of an entirely new standard for determining ozone depletion potential. Is the SNAP program planning to subject these standards to the review of new and previously approved compounds? If not, what warrants a change in SNAP program standards for nPB?

Industry sponsored workplace exposure assessments by pre-eminent scientists with recognized expertise in setting workplace safety guidelines are the basis for a consensus among industry participants that a 100 ppm WEL is appropriate. Yet, despite SNAP's clear policy and history of deference to industry recommendations, the EPA appears intent on recommending a 25 ppm WEL. Such an arbitrary action ignores credible scientific assessments, the industry's expert opinion, and EPA's own policy. It is difficult to understand the EPA's intentions in this instance. If EPA does, indeed, have valid, significant concerns about nPB, we would hope that you would

share them with industry. Unfortunately, to date, no information like that has been forthcoming from the agency.

As a strong proponent of the environment, I am also very concerned that EPA has chosen to operate under a veil of secrecy which has replaced partnership with suspicion and resulted in legal action under the Freedom of Information Act. EPA has refused to disclose the results of prior studies and tests about this chemical. No less than five draft reports (apparently evaluating the same data) are being withheld by EPA. I believe all documents requested under FOIA should be made available immediately to the public for their comment. Additionally, I request that these documents be sent to my office for review.

Inconsistency and shifting standards in the new alternatives arena can only have chilling effect on the willingness of industry to continue to fund research and development, thereby limiting the advancement of technologies favorable to our environment. I am gravely concerned that a program by which Congress intended to encourage new technology through government partnership with industry has become a barrier to innovation. At the same time, I am very concerned that this process may be undermining, and substituting itself in place of OSHA regulation of the workplace.

I would appreciate a full explanation regarding these concerns and a report on the current content and status of this rule making. Please have this information provided to me by April 30th.

I believe that a six-year review process is unacceptable. Combined with a disregard for the scientific assessments of the nPB compound, EPA's action is outrageous.

Thank you for your prompt attention to this matter.

Sincerely,

Frank Pallone, Jr.
Member of Congress

Cc: Jeffrey R. Homstead,
Assistant Administrator for Air and Radiation

FACT SHEET on nPB Review

- EPA's SNAP program was created under Section 612 of the Clean Air Act.

- Epidemiological and animal toxicological studies indicate that elevated exposure to nPB may impair reproductive, liver, kidney, and neurological function. An isomer of nPB appears to be highly toxic, causing sterility in exposed workers.

- Reports from industry and the National Institute of Industrial and Occupational Safety and Health indicate that workers using nPB as a solvent can be exposed to relatively high levels. In the absence of workplace standards established by the Occupational Safety and Health Administration or another government or industry standard-setting body, EPA's SNAP program has traditionally issued recommended workplace guidelines for chemicals under review. An evaluation was needed for nPB of potential risks to workers, and the general public living near facilities where nPB is used. To resolve uncertainties pertaining to key parameters, especially reproductive functions, nPB manufacturers agreed to conduct a multi-generation toxicological study. Results were released last summer in a report of several thousand pages; our consultant's analysis of the data is available in EPA's Air Docket (Docket number A-2001-07).

- nPB appeared to be a threat to stratospheric ozone despite its short atmospheric lifetime. EPA convened a meeting of academic and industry experts who agreed that a more detailed modeling approach was necessary. Our review incorporates the most recent analyses.

- The Technology and Economic Assessment Panel that reports to the Parties of the Montreal Protocol has issued several warnings on the ozone depletion potential and toxicity of nPB.

JOHN SULLIVAN
1ST DISTRICT, OKLAHOMA

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Congress of the United States
House of Representatives
Washington, DC 20515

COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE
SUBCOMMITTEE ON AVIATION
SUBCOMMITTEE ON ECONOMIC DEVELOPMENT, PUBLIC BUILDINGS, AND EMERGENCY MANAGEMENT

June 5, 2002

The Honorable Christine Todd Whitman
Administrator
Environmental Protection Agency
Ariel Rios Federal Building
1200 Pennsylvania Avenue, N.W.
Room 3000
Washington, D.C. 20004

Dear Administrator Whitman:

It has come to my attention that the long awaited outside consultant report on "n propyl bromide" (nPB) has finally been submitted to the Significant New Alternatives Program (SNAP) docket. I also understand that the findings and recommendations of the consultant's report continue to generate controversy among the nPB industry and the scientific community.

As you know, due to increasing concern over EPA's scientific practices, the House of Representatives, by a resounding, bipartisan majority, recently passed H.R. 64, establishing the position of Deputy Administrator for Science and Technology of the Environmental Protection Agency. This legislation is designed to strengthen the role science plays in decision-making at the regulatory level. As EPA begins its final determination and rulemaking process on nPB, and on any petition under its preview, I would urge that you utilize sound, scientific practice.

I will be watching with interest as your agency completes its action on the nPB petition.

Sincerely,

John Sullivan
Member of Congress

Cc: Dr. John Graham, Administrator
Office of Information and Regulatory Affairs

Jeffrey R. Homstead,
Assistant Administrator for Air and Radiation

Frank Keating
Governor

April 23, 2002

The Honorable Christine Todd Whitman
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Dear Administrator Whitman,

In June, 2001, I wrote to you on behalf of concerned businesses in Oklahoma urging evaluation of a proposed rule enacted by the previous administration which would have established allocation systems for hydrochlorofluorocarbon production, imports and exports. I am now advised of, and call to your attention, rulemaking related to nPropyl Bromide (nPB) as it impacts the operations of such firms as Enviro Tech in Illinois and TULSTAR Products, Inc., of Oklahoma.

It would appear that SNAP approval has been delayed concerning nPB, and that unique and excessively stringent rules and procedures are being applied in this case. I would refer you to previous letters on behalf of Enviro Tech by Congressmen Rush and Shimkus, and to the concern raised by TULSTAR in hopes that EPA will reevaluate nPB for VOC exemption under the same standards used to evaluate other chemicals.

I am also informed that delays and other actions have caused these, and perhaps other companies, to incur excessive expenses. I hope the agency will look closely at all factors involved in this matter, and proceed in the most fair and expeditious manner.

Sincerely,

Frank Keating

fak/mb

STATE CAPITOL BUILDING • OKLAHOMA CITY, OKLAHOMA 73105 • (405) 521-2342 • FAX (405) 521-3353

The Honorable Frank Keating
Governor
State Capitol Building
Oklahoma City, OK 73105

Dear Governor Keating:

Thank you for your letter of April 23, 2002 on behalf of Enviro Tech International and TULSTAR Products, Inc. concerning the U.S. Environmental Protection Agency's (EPA's) process for reviewing n-propyl bromide (nPB). I want to assure you that nPB is undergoing the same review as other chemicals submitted to EPA under the Significant New Alternatives Policy (SNAP) program and under the Agency's process for issuing VOC exemptions.

The SNAP program was established under the 1990 Clean Air Act Amendments to require EPA to evaluate overall risks of substitutes for ozone-depleting substances compared to other alternatives. The SNAP program assesses every substitute for its potential impacts on health and the environment. The length of individual reviews depends on the nature of the chemical, how it is used, and the completeness of the available data. This chemical has warranted a careful review for several reasons summarized in the enclosed fact sheet. EPA is working hard to issue a decision expeditiously and the Agency expects to publish a proposed rulemaking for public comment this summer.

EPA is currently reviewing Enviro Tech's request for an exemption from the requirements for volatile organic chemicals (VOCs). The Agency considers each chemical using the same criteria. There must be sufficient evidence that a chemical is no more photochemically reactive than ethane. EPA's Air Quality Strategies and Standards Division in the Office of Air Quality, Planning and Standards is continuing to work with Enviro Tech to resolve outstanding technical issues.

The Agency has conducted an open process in its review of nPB. We have published notices in the Federal Register in 1999 and 2000 to share the latest information with the public. There are over 100 documents on nPB in our public dockets, including a major report on the toxicity of nPB that Enviro Tech has requested from the Agency. Since 1997, we have attended ten industry conferences and have met with numerous companies to provide continual updates. In the past 18 months alone, we have met with representatives of Enviro Tech on five occasions concerning EPA's ruling under the SNAP program, as well as additional meetings to discuss the

petition for a VOC exemption. EPA has also exchanged correspondence on a number of occasions with both TULSTAR and Enviro Tech.

Again, thank you for your letter. A more detailed response to the issues raised by Congressmen Rush and Shimkus is enclosed. I appreciate the opportunity to be of service and trust the information provided is helpful. If you have questions concerning EPA's review of nPB, have your staff contact Brian McLean, Acting Director of EPA's Office of Atmospheric Programs, at (202) 564-9154.

Sincerely yours,

Christine Todd Whitman

Enclosure

FACT SHEET on nPB Review under the SNAP Program

- EPA's SNAP program was created under Section 612 of the Clean Air Act.

- Epidemiological and animal toxicological studies indicate that elevated exposure to nPB may impair reproductive, liver, kidney, and neurological function. An isomer of nPB appears to be highly toxic, causing sterility in exposed workers.

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- The Technology and Economic Assessment Panel that reports to the Parties of the Montreal Protocol has issued several warnings on the ozone depletion potential and toxicity of nPB.

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EnSolv® precision cleaning solvent

Safety of n-propyl bromide (nPB) more rumours and innuendo

Rumours in the industrial press and various websites and blogs are suggesting there are proposals by ACGIH for a reduction of the current recommendations for exposure limits for n-Propyl Bromide. This solvent is widely used as an alternative to trichloroethylene for vapour degreasing. As there is no official exposure limit for nPB (n-Propyl Bromide) in Europe or the USA, it is difficult to give credence to this campaign of innuendo emanating from manufacturers of fluorocarbon solvents who market modified trans 1,2 Dichloroethylene based cleaners.

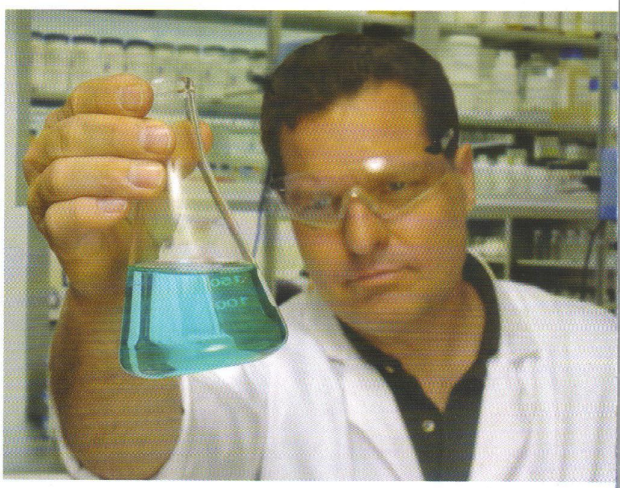
ACGIH is an industry body in the United States, paid for and dominated by major chemical companies whose "experts" are nominated for the evaluation panels. Figures for TLVs issued by ACGIH are purely their opinion and not adopted by any authority including the U.S. EPA who rejected their proposals when issuing SNAP acceptance of nPB as a vapour degreasing solvent in the U.S.
The U.S. EPA rejected the current ACGIH TLV of 10ppm and instead recommended 25ppm under normal conditions of use. However even this is not an official figure as only OSHA can set exposure standards in the U.S.

The EU will establish DNEL (Derived No Effect Level) recommendations in due course under the REACH legislation.

The manufacturers of **EnSolv**, the market leading nPB based vapour degreasing solvent formulation, commissioned leading authorities to examine the very large database of exposure studies for nPB and their work clearly demonstrates that an LTEL of 100ppm offers complete safety for personnel. Exposure studies in Europe submitted to ECHA demonstrate that even simple vapour degreasers can control emissions of nPB to less than 25ppm.

As the manufacturers of **EnSolv** we can assure users and potential clients that until an official exposure limit is issued under the REACH legislation all properly designed and maintained equipment will be perfectly safe for use and offer the most economical and highest standards of cleaning.

EnSolv distributors are trained to inspect and advise on the use of the vapour degreasing process for economical and safe usage with monitoring and exposure testing on request.



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DrySolv™ from Dry Cleaning Technologies, a division of Enviro Tech International Inc, is the newest environmentally responsible solvent development on the market. It comes on the heels of major Perc regulations and is the most viable new alternative. DrySolv™ was developed 11 years ago under a different trade name, EnSolv, in the vapor degreasing industry. EnSolv is a variation of the DrySolv™ chemistry that has matured into an internationally known solvent and has been approved by large organizations such as Boeing to be the only environmentally friendly alternative used to replace harsher solvents. It is the only patented chemistry of its kind and has proven to be the leading alternative solvent in that industry.

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DrySolv™ is not listed or expected to be a carcinogen.

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DrySolv™ is also non-chlorinated.

DrySolv™is non-hazardous.
(DOT, OSHA, NESHAP, RCRA, Clean Water Act)

DrySolv™ is not a hazardous air pollutant, is SNAP approved and does not contribute to global warming.
(NESHAP, Significant New Alternative Program-SNAP approved (Federal EPA), Not Title V)

The USEPA states that DrySolv's™ main ingredient is less persistent in the environment than many other solvents, is of low to moderate concern for movement in soil, does not warrant listing under the Toxics Release Inventory and is not prone to bioaccumulation. (USEPA - Federal Register May 30, 2007).

DrySolv™ **does not** have a hazardous decomposition or hazardous polymerization.

Veoila Environmental Services, a nationally known waste service company, has established their Drum Express licensed waste-hauling program specifically for DrySolv™ users.

Dry Cleaning Technologies
PO Box 293 • Harmony, PA • (724) 473-8117 • fax (724) 473-8119

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a division of ENVIRO Tech International, Inc.

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As for the Dry Cleaners….

DrySolv™ will work in their existing class IV Perc machine as a "drop in" replacement. It will do a superior job at cleaning garments then Perc in a shorter time, while using less energy to do so.

DrySolv™ is the best alternative for Dry Cleaners to date. The chemistry has an 11-year track record of award winning, environmentally friendly excellence. We at Dry Cleaning Technologies hope to pass this legacy on to the dry cleaners of today assuring a safe and clean future for us all.

Please feel free to contact me direct with any questions or concerns.

Best Regards,

Ray Roccon 724-473-8117 rroccon@dctco.com
Division Manager